EXHIBIT K

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: ETHICON, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	Master File No. 2:12-MD-02327 MDL NO. 2327
	JOSEPH R. GOODWIN U.S. DISTRICT JUDGE
THIS DOCUMENT RELATES TO PLAINTIFFS: Ida Evans 2:12-cv-01225 Rose Gomez 2:21-cv-00344 Jeanie Holmes 2:12-cv-01206 Mary Jane Olson 2:12-cv-00470 Christine Wiltgen 2:12-cv-01216 Kathleen Wolfe 2:12-cv-00337 Monica Freitas 2:12-cv-01146 Denise Sacchetti 2:12-cv-01148 Sheri Scholl 2:12-cv-00738 Cindy Smith 2:12-cv-01149 Waynick, Laura 2:12-cv-01151	APRIL 18, 2016

DEPOSITION OF STEVEN MACLEAN, Ph.D, P.E.

Caption Continued:
Denise Burkhart : 2:12-cv-01023 :
Jo'Ann Lehman : 2:12-cv-00517 :
Patricia Ruiz : 2:12-cv-01021 :
Pamela Free : 2:12-cv-00423 :
Melissa Ridgley : 2:12-cv-01311 :
Marty Babcock : 2:12-cv-01052 :
Dorothy Baugher : 2:12-cv-01053 :
Patti Ann Phelps : 2:12-cv-01151 :
Lisa Thompson : 2:12-cv-01199 :
Rebecca Wheeler : 2:12-cv-01088 :
Thelma Wright : 2:12-cv-01090 :
Rocio Herrara-Nevarez : 2:12-cv-01294 :
Debra A. and Donald Schnering : 2:12-cv-01071 :
Rebekah Bartlett (Pratt) : 2:12-cv-01273 :
Amanda Deleon : 2:12-cv-00358 :

Caption Continued:
Karyn Drake : 2:12-cv-00747 :
Paula Kriz : 2:12-cv-00938 :
Stacy Shultis : 2:12-cv-00654 :
Kimberly Thomas (Wyatt) : 2:12-cv-00499 :
Patricia Tyler : 2:12-cv-00469 :
Myndal Johnson : 2:12-cv-00498 :
Beverly Kivel : 2:12-cv-00591 :
Karen Bollinger : 2:12-cv-01215 :
Virginia Dixon : 2:12-cv-01081 :
Shirley Walker : 2:12-cv-00873 :
Dawna Hankins : 2:12-cv-00369 :
Wilma Johnson : 2:11-cv-00809 :
Margaret Kirkpatrick : 2:12-cv-00746 :
Harriet Beach : 2:12-cv-00476 :
Holly Jones : 2:12-cv-00443 :

Deposition of STEVEN MACLEAN, Ph.D., P.E., taken before and by Janis L. Ferguson, Notary Public in and for the State of New York, on Monday, April 18, 2016, commencing at 8:41 a.m., at the Rochester Airport Marriott, 1890 Ridge Road West, Rochester, New York 14614.

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INDEX

I N D E X (Continued)

S T E V E N M A C L E A N, Ph.D., P.E., first having been duly sworn, testified as follows:

EXAMINATION

BY MR. THORNBURGH:

Q. Good morning, Dr. MacLean.
A. Good morning.
Q. How are you?
A. I'm well. How are you?
Q. Good. My name is Daniel Thornburgh. And you and I have met before in a prior deposition?
A. We have.
Q. And you understand that you're here to give deposition testimony in the Wave 1 cases?
A. Correct.
Q. Okay. And you've given deposition testimony before, and so you know the ground rules. I'm not going to go through all of them.

But I would ask that if you don't understand a question that I ask, let me know. Okay?
A. (Witness nods head.)
Q. If you answer the question, I'm going to assume that you understood it, and then we'll just move forward. Okay?
A. Understood.
Q. And I'm not, obviously, a polymer scientist, I'm not an expert, so I may ask a question poorly. If I do, just let me know.
A. Will do.
Q. I want to make sure that we have a clean record. Okay?
A. Understood.
Q. And you understand that you're under oath?
A. I do.
Q. And that you need to provide truthful and accurate testimony.
A. That's correct.
Q. Have you given any depositions since the last time you and I met?
A. I believe there are two, yes.
Q. In what cases?
A. I don't remember.
Q. Is it on your testimony list?
A. It should be, yes. The two cases that I recall are Brunswick v. Slocum, and the second case is Hower v. Excel.
Q. So Brunswick versus Slocum?

A. (Witness nods head.)
Q. What does that case concern?
A. That was involving adhesive failure for wood laminates.
Q. Okay. And did you -- were you retained in that case to offer expert opinion testimony on behalf of the Defendant manufacturer?
A. For Slocum, correct. The adhesive manufacturer.
Q. And what's the second case again?
A. Hower v. Excel. H-O-W-E-R v. -- and Excel is E-X-C-E-L.
Q. And what was the nature of that case?
A. That was a products case involving a ride-on lawnmower.
Q. And so the Plaintiff is alleging some sort of defect with the riding lawnmower?
A. Yes. Specifically, the fuel system and the fuel lines.
Q. Okay. And you represented Excel, the Defendant, in that lawsuit?
A. That's correct.
Q. And that was a Defendant manufacturer?
A. That's correct.

Q. And did you offer testimony in your capacity as an employee for Exponent?
A. I offered expert testimony as an expert in polymer science.
Q. As an employee of Exponent.
A. As an employee of Exponent, correct.
(Discussion held off the record.)
Q. Doctor, before we mark this exhibit, you haven't personally analyzed any explanted polypropylene meshes, correct?
A. I have.
Q. Okay. Since -- did you do that in this case?
A. I did that in the last few months, over the last few months.
Q. Okay.
A. It was with regard to certain explants from Wave 1.
Q. Which Wave 1 explants did you analyze?
A. (No response.)
Q. Did you do a case-specific report?
A. I did -- for those particular explants?
Q. Right.
A. I did not.
Q. Okay.

A. The first one is Kathy Barton, B-A-R-T-O-N. The second one is Michelle Bellito-Stanford. B-E-L-L-I-T-O. The third one is Barbara Bridges, B-R-I-D-G-E-S. Mary Jean Simpson. Margaret Stubblefield, S-T-U-B-B-L-E-F-I-E-L-D. Charlene Taylor, T-A-Y-L-O-R. And last one is Mary Wise-Turner, W-I-S-E - T-U-R-N-E-R.
Q. Are these the first set of explanted mesh material that you've analyzed as a polymer scientist?
A. Analyzed, no, because I've analyzed scores of data from other explants.
Q. Data that was reported by other -- other witnesses, other experts?
A. By other researchers, experts, Ethicon themselves, correct.
Q. But this is the first time -- this batch of Plaintiffs, this is the first time that you've personally conducted or oversaw the analysis of explanted mesh material.
MR. THOMAS: Object to form of the question.
A. This will be at least the second time, because I did some work with the blue explant a few years ago. A year or so ago.
Q. What work did you do with the blue explant?

A. Just examined it under the microscope after the case was either settled or dismissed. I can't recall the outcome of that case.
Q. There was some leftover material from that lawsuit that you analyzed?
A. Correct.
Q. And what was the purpose of analyzing the blue material?
A. Just to look at the mesh with the tissue around it.
Q. Because you had not done it previously?
A. Not prior to that.
Q. So you were just trying to get sort of an idea of what it looked like?
A. I would say to just have an opportunity to see it first-hand.
Q. What did you do? Just look at it by optimum microscopy?
A. Looked at it optically. Also looked at it under scanning electron microscopy.
Q. Okay. And you didn't perform any FTIR or any other analysis?
A. I don't believe so. On that particular mesh.
Q. We'll get back to the Plaintiffs that you've

looked at their mesh specimens later on today. Okay?
A. Okay, sure.
(MacLean Deposition Exhibit 1 - Notice of Deposition - marked for identification.)
Q. Doctor, I've marked as Exhibit No. 1 the Notice of Deposition. Have you seen this document before?
A. I have.
Q. And attached to the Notice and the Schedule A that asks for a set of document requests, have you gone through this Schedule A to look for any documents that were responsive to this request?
A. I have.
MR. THOMAS: Dan, just so you know, you know we filed a response to the Notice?
MR. THORNBURGH: Okay.
MR. THOMAS: Okay?
Q. Were there any documents that you felt were responsive to the request that you did -- that you did not produce?
MR. THOMAS: Objection. There are a number of the documents that we've objected to producing in the response to the -- to the Notice. If you want to go through those one

by one, I'm happy to, but I think you'll find that his complete file that he relies on for his opinions in the case has been produced.

Q. Let me ask you this question: Did you conduct any testing or analysis of -- in this litigation that you did not produce the underlying data for?

A. No.

Q. So you've produced all of the underlying data related to all of the testing that you conducted in this case.

A. For Wave 1, yes, correct.

Q. For Wave 1. And that was produced to me electronically yesterday. I wasn't able to print out any -- hardly any documents from that. Did you bring any documents with you today? I see some notebooks.

A. I did.

Q. Let's go ahead and mark those documents.

A. Okay.

MR. THOMAS: For your information, Dan, he's got a thumb drive in his computer which is the complete set of what was sent to you yesterday. If you want to mark the thumb drive as well.

MR. THORNBURGH: Yeah. We'll go ahead and mark the thumb drive as well. Let's mark the thumb drive as Exhibit No. 2.

MR. THOMAS: I'll put the sticker on it.

(MacLean Deposition Exhibit 2 - Thumb Drive - marked for identification.)

BY MR. THORNBURGH:

Q. Okay, I'm going to mark as Exhibit No. 3 a binder that you brought with you today that appears to be your expert report.

A. Correct.

(MacLean Deposition Exhibit 3 - Expert Report of Dr. Steven MacLean - marked for identification.)

Q. I'm going to thumb through it real quickly.

A. By all means.

Q. And there's some highlighting on this report. Are these highlighting -- is this highlighting that you made?

A. My highlighting, correct.

Q. On Exhibit 3, there's a tab. Can you tell me what that tab says. It's on Page 68 of your expert report. I just can't read your handwriting.

A. Yep. No, that's fine. It's Becke,

B-E-C-K-E.

Q. And what does "Becke" mean?

A. It's -- refers to a Becke line, which can be an artifact of optical microscopy.

Q. Okay. We'll talk about that in a little bit. Do you have any -- other than what's contained with your report, did you bring any hard copies of the microphotographs?

A. Very few. I have them all on the thumb drive, so if there's one particular one you want to focus in on, we can certainly pull it up.

Q. Okay. Does Appendix G of Exhibit 3 contain all of the microphotographs that you took in this case?

A. It does.

Q. Did you take additional microphotographs in your supplemental report of the work that you conducted in the -- to produce the supplemental report?

A. Yes.

Q. Let's go ahead and mark Exhibit No. 4.

(MacLean Deposition Exhibit 4 - Wave 1 Supplemental Report of Dr. Steven MacLean - marked for identification.)

Q. That is your supplemental report. I'll thumb through it really quick.

Okay. And Exhibit No. 4, there are a number of separated -- looks like two microphotographs or copies of microphotographs of -- it looks like the chemical-treated specimens.

A. Correct.

Q. I'm going to go ahead and mark those separately as Exhibit No. 5.

(MacLean Deposition Exhibit 5 - Microphotograph - marked for identification.)

Q. And Exhibit No. 6.

(MacLean Deposition Exhibit 6 - Microphotograph - marked for identification.)

Q. I don't see an appendix on exhibit to your supplemental report that contains the images that we saw in your original report, which was the microphotographs. Is it fair to say that you did not attach the microphotographs to your -- strike that.

Is it fair to say that you did not attach to your supplemental report, or at least what you brought with you today, the microphotographs of the work that relates to the supplemental report?

A. I did not print hard copies of those,

correct. But, again, they're on the hard drive.
Q. Right. I'll hand you back Exhibit No. 3 and 4.
(Discussion held off the record.)
Q. We'll just keep those out so the court reporter can find them as well.
A. Sure.
(MacLean Deposition Exhibit 7 - Binder of Published Literature of Dr. Steven MacLean - marked for identification.)
Q. Okay. We've marked as Exhibit No. 7 a binder that you brought with you today that appears to be some published literature?
A. (Witness nods head.)
Q. Is that correct?
A. It is correct.
Q. There are a couple of additional documents in the sleeve of Exhibit No. 7 that I'll mark as separate exhibits. The highlighting that's contained within -- or on any of these publications, who highlighted those?
A. I did.
Q. And are the electronic copies of those publications also contained on your thumb drive?

A. They are.
Q. I'll mark as Exhibit No. 8 the Clavé article, which was in the sleeve of Exhibit No. 7.
(MacLean Deposition Exhibit 8 - Clavé Article - marked for identification.)
Q. And looks like a summary of some of the publications. Correct?
A. Correct.
Q. Which I'll mark as Exhibit No. 9.
(MacLean Deposition Exhibit 9 - Summary of Publications - marked for identification.)
Q. Who drafted the summaries of these publications?
A. I did.
Q. When did you draft this?
A. Several weeks ago.
Q. Was that in conjunction with the work that you did on the supplemental report?
A. I would say it was during the same time as the supplemental report was being drafted.
Q. Did you make any notes of any of the publications prior to submitting your Wave 1 report?
A. Those would be the only notes I have on the literature that I've taken. I don't recall the timing.

Q. Was the first time that you looked at the -- did you first read the articles that are summarized in Exhibit No. 9 in conjunction with the work that you did in your -- in drafting your supplemental report?
A. Could you just repeat that.
Q. Yeah.
MR. THORNBURGH: Can you read that back.
(Record read back by the reporter.)
A. No. Many of those pieces of literature I read over a year ago.
Q. Okay. So this was just a re-review of the articles --
A. Correct.
Q. -- and publications?
A. Correct. Just to try to keep it all straight.
Q. When we met in the Mullins litigation and I took your deposition, you had issued a report in that case; the consolidated TVT set of cases. And you had testified during your deposition that you had help from your technicians or staff members at Exponent in drafting your expert report in the Mullins case.
A. I had some assistance with some of the sections of the report, correct. Initial drafts of the

report.
Q. Okay. Did you have any assistance in -- from your staff or technicians in drafting your first expert report, your primary expert report that was issued in the Wave 1 cases?
A. I did, but it was fairly limited, because the -- it was only some additional sections from the Mullins report that were added into the supplemental.
Q. I'm talking about --
A. I'm sorry.
Q. -- the initial report, yes.
A. Yes.
Q. And then what about your supplemental report? Did you have assistance in drafting that report from staff members or employees of Exponent?
A. I did. I had two colleagues that assisted with that work.
Q. And what are their names?
A. Dr. Garcia and Dr. Benight.
(Witness asked for clarification by the reporter.)
A. B-E-N-I-G-H-T.
Q. And who helped you with drafting the -- some of the sections in your Wave 1 primary initial report?

A. Dr. Moll.
Q. Okay.
A. And Dr. McGann. M-O-L-L, M-C-G-A-N-N.
Q. For your first report in Wave 1 -- we'll call it your primary report -- what sections were drafted by the employees of Exponent?
A. I think we'd have to go look at the report and look at the additional sections.
(Discussion held off the record.)
A. So Dr. Moll and I had worked on the Mays section, M-A-Y-S. Dr. McGann and I worked on the Priddy section, P-R-I-D-D-Y. And Dr. Moll and I worked on the Klinge, K-L-I-N-G-E, section.
Q. And are those -- those sections represent the only additions to your report that was issued in the Mullins case?
A. Not exactly. So in this -- in the Wave 1 report, I consolidated the original microscopy report with the Mullins report, so that, arguably, is also an addition.
Q. Right.
A. And I think that is the total of the additions, compared from -- Mullins, compared to Wave 1.

Q. Okay. And regarding your supplemental report, which I think was marked as Exhibit No. 3 -- 2 or 3 --
MR. THOMAS: 4.
Q. I'm sorry, 4. Who, again, helped you with that report?
A. I'm sorry. Which report?
Q. You said Dr. Benight and another doctor.
A. And Dr. Garcia.
Q. Dr. Benight and Dr. Garcia helped you draft the additional sections that were added to the supplemental report?
A. I just want to make sure we have all the reports --
Q. Exhibit No. 4.
A. So just ask me that one more time.
Q. Yeah. Dr. Benight and Dr. --
A. Garcia.
Q. -- Garcia, they helped you draft certain sections of the supplemental report. Right?
A. Correct. That's correct.
Q. Which has been marked as Exhibit No. 4. Which section did those doctors or those technicians assist you with?

A. They're not technicians. They're -- they are Ph.D. scientists. And I don't recall which sections exactly. We went through that report several times. I couldn't parse out which sections they helped with and which ones they didn't.
Q. Okay. Well, we'll go through it --
A. Okay.
Q. -- in greater detail.
A. Sure.
Q. I'm going to hand you back Exhibit No. 7, which is the published literature.
A. Okay.
Q. Here is Exhibit No. 8, which is your marked-up copy of the Clavé study.
A. Thank you.
Q. And Exhibit No. 9, which is your summary of some of the publications.
I'll mark as Exhibit No. 10 a binder that you brought with you that appears to be copies of certain expert reports from the Plaintiffs.
(MacLean Deposition Exhibit 10 - Plaintiffs Experts' Reports - marked for identification.)
A. Correct.

Q. In the sleeve, there appears to be a deposition excerpt from Dr. Priddy.
A. Correct.
Q. I'll mark that as a separate exhibit, No. 11.
(MacLean Deposition Exhibit 11 - Excerpt of the testimony of Duane Priddy, Ph.D. - marked for identification.)
Q. It's two pages. It's 139 and 140 of Dr. Priddy's deposition.
A. Correct.
Q. And this is an excerpt -- was this excerpt provided to you by Ethicon's counsel?
A. No. The entire deposition was provided to me from Ethicon's counsel. That was an excerpt that I took out and highlighted.
Q. Okay. And so you did the highlighting of this -- on this document?
A. Correct. I read his entire deposition, and I highlighted those sections and pulled them out.
Q. Okay. And there's some flags on Exhibit No. 10. Are those flags done by you?
A. They were done by me.
Q. It looks like all of these flags relate to the expert report of Dr. Iakovlev.

A. It would appear. Just show me the yellow one. You are correct.
Q. Okay. Are there any documents or materials that you brought with you today that we have not marked?
A. No. I believe that's everything.
Q. Dr. MacLean, when were you retained by Ethicon as an expert in the Wave 1 cases? Actually, this might help you out.
(MacLean Deposition Exhibit 12 - June 15, 2015 letter from Steven MacLean to Chad R. Hutchinson - marked for identification.)
Q. I've marked as Exhibit No. 12 a letter -- looks like it's from Exponent to Chad Hutchinson, which is a lawyer for Butler Snow, representing Ethicon. It looks like a retention letter.
A. That is correct.
Q. Okay. So based on -- according to the retention letter, you were retained formally by letter -- or you accepted the request to be retained on June 15th, 2015. Is that correct?
A. Correct. That's when this formal letter was written.
MR. THOMAS: And just to be fair, it's

general consulting. I don't think Wave 1 existed at the time this letter was written.
MR. THORNBURGH: Okay.
Q. So this was general consulting for future work -- future unknown work to be conducted on behalf of -- or as an expert employed at Exponent, representing Ethicon.
A. It's a retention for mesh-related matters, correct.
Q. What's your hourly fee, again?
A. In 2016, it's 380.
Q. 380. So at the time --
(Discussion held off the record.)
Q. At the time that you were retained as a general expert in June of 2015, your hourly rate was -- appears to be $355 per hour?
A. In 2015, correct.
Q. Okay. And it has gone up in 2016 to $380 per hour?
A. It is now $380 an hour, correct.
Q. All right. You also produced a number of invoices. We'll mark it as Composite Exhibit No. 13.
(MacLean Deposition Exhibit 13 - Invoices - marked for identification.)

Q. Which Composite Exhibit 13 contains an invoice from July 17th, 2015, in the amount of $72,174. So about a month after your -- the retention letter, you invoiced Ethicon in this amount. Correct?
A. Correct.
Q. So the $72,174, does that represent payment for the work that was conducted by you or by Exponent related to the retention letter of June 15th, 2015? Is that all work -- strike that.
Does that invoice represent work that was conducted by you or Exponent after the June 15th, 2015 retention letter?
A. For my projects, correct.
Q. Okay. So in less than a month, you and/or Exponent billed Ethicon for $72,174.
A. We provided services that equated to $72,174.
Q. Okay. What services did you provide from June 15th, 2015 to July 17th, 2015 which represent the billing of $72,174?
A. Consulting services.
Q. What type of consulting services?
A. We were working on -- at this time we would have been working on the Mullins consolidated cases. So I would -- without having any more detail, this work

would have been in support of that effort, primarily.
Q. When did you begin your work for the Wave 1 cases?
MR. THOMAS: Object to form of the question.
A. I don't recall a specific date.
Q. If you look at the next invoice, it's dated August 13th -- let's see here. August 13th, 2015. And the August 13th, 2015 invoice, which is about a month later from the last invoice that we looked at, is in the amount of $19,848. Correct?
A. Correct.
Q. Was this -- did this -- the work that you conducted and billed for this August 13th invoice, does that relate to the work that you did in the Wave 1 litigation?
A. For the -- I'm sorry; for which invoice? The August 13th invoice?
Q. August 13th.
A. No. This would not have included Wave 1.
Q. The next invoice is dated October 30th, 2015. I'll hand you a copy of that. And this invoice, it doesn't have a total. Doesn't appear to be totaled. Right?
A. It does not appear to be totaled, unless the

second page is perhaps missing.
Q. And it looks like it's somewhere north of a hundred thousand dollars. Right? I didn't do the math, but somewhere north of a hundred thousand?
A. It's probably somewhere between 90 and a hundred thousand dollars.
Q. Okay. And does the work that's reflected on the invoice of October 30th, 2015, which is just two months later from the last invoice, does that represent any work that was conducted by you or Exponent as it relates to the Wave 1 litigation?
A. My best recollection is no, that this is still prior to Wave 1.
Q. Okay. December 29th, 2015 is the next invoice that was produced. And this is an invoice in the amount of $34,781.70. Approximately two months since the last invoice. Does any of the work contained on the December 29th, 2015 invoice relate to the work that was conducted by you in Wave 1?
A. I don't believe so.
Q. Here's the January 21st, 2016 invoice. It looks like this is in the amount of $6,078. Is that -- does this invoice represent any work that was conducted by you in Wave 1?

A. Most likely.
Q. Okay. Would this indicate to you approximately the time that you would have been retained in the Wave 1 --
A. I wouldn't use the word "retained". I think our Wave 1 discussions and conversations started in or around the 1st of January.
Q. So is it fair to say that all of the invoices after January 21st, 2016 would relate to the work that you conducted in the Wave 1 litigation?
A. No, not necessarily. Actually, I take that back. With regards to this project number, yes.
Q. Okay. So Project No. 1504469 would -- would represent the project number for the Wave 1 work?
A. And -- and Mullins, correct.
Q. Okay. So January 21st, 2016 is an invoice, again, for $6,078. The next invoice is a month later; approximately February 23rd, 2016. It's not totaled, but would be somewhere between 30- and $40,000?
A. Approximately.
Q. The next invoice I have is March 16th, 2016. Again, this invoice is not totaled, but it would appear to be somewhere north of -- somewhere close to a hundred thousand?

A. Roughly between 90 and a hundred thousand.
Q. And I've got another invoice that is out of order. This is from November 24th, 2015, so before the work that you conducted on Wave 1. I have marked that -- or it's already marked, but I'll hand it over to you.
And this invoice is also not totaled, but it looks -- appears to be somewhere around $80,000, approximately. A little more than that.
A. Somewhere in that ballpark, correct.
Q. Okay. So the -- and you've -- going back to the last invoice, March 15th, 2016, you have and Exponent has conducted additional -- or has performed additional services or work for Exponent [sic] since March 15th, 2016, correct?
MR. THOMAS: Object to form. I think you --
A. Yeah.
MR. THOMAS: -- said we did the work for Exponent.
Q. I'm sorry. Let me re-ask the question.
Since the March 15th, 2016 invoice, Exponent or yourself has performed additional services on behalf of Ethicon, correct?
A. Are you asking me since March 15th?

Q. Yeah. There would be additional billing, right?
A. Yeah. Sure.
Q. Okay. And what work has been conducted by you or Exponent related to the Wave 1 cases since the March 15th, 2016 invoice? If you know.
A. I don't think I know specifically, without looking at the -- I would say the pending or the current invoices which have not been generated yet. I suspect some of them would have been related to my deposition prep.
Q. And how much time have you spent prepping for the deposition?
A. I don't -- I don't know a number.
Q. 20 hours or more?
A. I think, yeah, probably 20 to 30 hours.
Q. And does that include prep that you've -- strike that.
Does that include meetings that you've held or had with Ethicon's counsel in preparation for the deposition?
A. Yes, that would include that.
Q. Okay. And when did you meet with Ethicon's counsel to prepare for the deposition?

Page 34

A. Dr. -- excuse me. Mr. Thomas and I met last night for a few hours.
Q. How many hours did you meet last night to prepare for the deposition?
A. Probably two.
Q. We're done with the invoices. Just keep those invoices together, because they're a composite exhibit.
Doctor, I'm going to go ahead and mark my copy of your expert report, the primary expert report that was issued in Wave 1, as Exhibit No. 14.
(MacLean Deposition Exhibit 14 - Copy of Expert Report of Dr. Steven MacLean - marked for identification.)
Q. I've remarked it just so that we could navigate easier, because I've got my own marked-up copy, so.
But your Wave 1 expert report, if you turn to the -- maybe the first page, it shows a date of March 1st, 2016.
A. Correct.
Q. Okay. And is that -- to your recollection, is that when you had finished and signed your Wave 1 first report? Approximately.

Page 35

A. I don't recall, but I'll take the date at face value.
Q. Okay. And we're not going to spend a whole lot of time on your first report, because it's -- contains a lot of the same information and testimony that you had provided in the Mullins case. Okay?
A. (Witness nods head.)
Q. We may -- we might jump to it, but we're not going to spend too much time on it.
A. Understood.
Q. And after you had submitted your initial report in Wave 1, you then submitted a supplemental report, correct?
A. Correct.
Q. And the supplemental report was submitted late, after the deadline for expert disclosures? Do you --
A. I don't recall those dates. I can only go with what date was on the actual report.
Q. Why weren't you able to submit your supplemental report earlier?
A. Because the work that we were performing did not conclude, I think, until early March.
Q. So the work that is contained within your supplemental report did not conclude until, you said, early March?

Page 36

A. Yeah. I can give you a date.
Q. I'll go ahead and -- let's mark as Exhibit No. 15 my copy of your supplemental report.
(MacLean Deposition Exhibit 15 - Copy of the Supplemental Report by Steven MacLean - marked for identification.)
Q. Your supplemental report is dated March 22nd, 2016?
A. Correct.
Q. And the reason why you couldn't submit it earlier was because the work that you were conducting, which is contained within the supplemental report, wasn't yet complete.
A. Correct.
Q. Were you provided with a deadline for which the work needed to be completed for the Wave 1 cases?
A. No. I was not given a deadline.
Q. And the work that you -- that is reported in your supplemental report, the additional analysis of the TVT products, the hernia product, and the suture product, when did you begin that work?

Page 37

A. Off memory, in and around February 1st, 2016.
Q. And why don't you just briefly describe what additional experiments you did which are contained within your Wave 1 supplemental report.
A. Okay. So we sought to expand the previous work that we did. And so I acquired a number of different PROLENE products. As you mentioned, a TVT mesh, hernia mesh, PROLENE sutures. We also went out in the open market and bought an off-the-shelf grade of polypropylene from Sigma-Aldrich. And we deliberately oxidized those specimens under two defined protocols. And then after we oxidized them, they were microtomed and stained in H&E staining solutions. And we then did some microscopy work to determine if the stain was retained by any of those specimens.
Q. Okay. If we turn to Page 4 of your supplemental report, Exhibit No. 15, you have sort of the introduction of your report. Page 4. I'm sorry, Exhibit No. 15.
MR. THOMAS: That's the wrong one.
Q. There you go. Okay.
(Discussion held off the record.)
(Attorney Joseph Kramer joins deposition by teleconference.)

Page 38

Q. Back to Exhibit No. 15, Page 4, you sort of summarize the additional testing or materials that you analyzed for your supplemental report. Correct?
A. That is correct.
Q. And so it looks like you looked at three TVT samples, one hernia sample, and one suture sample. Correct?
A. Correct.
Q. Okay. And you conducted additional -- an additional experiment using the QUV oxidation. Correct?
A. Correct.
Q. Which is UV radiation, right?
A. It is.
Q. You intentionally oxidized the -- or your intent was to intentionally oxidize the samples using UV light?
A. Correct.
Q. And energy?
A. We irradiated the samples with UV light, correct.
Q. And you accelerated that -- that by increasing the temperature?
A. It was 60 degrees Celsius inside the chamber.

Page 39

Q. Okay. And how many pieces of the TVT device were subjected to the UV irradiation experiment?
A. There were several hundred individual fibers that were exposed to QUV.
Q. How many samples of the -- so I'm just trying to break this down. Okay?
A. Sure.
Q. You received three TVT pristine, in-the-package products from Ethicon. Correct?
A. (No response.)
Q. If you turn to Page 9 -- maybe this will help you out. If you turn to Page 9 of your supplemental report.
A. (Witness complies.)
Q. You talk about sample preparation.
A. Correct.
Q. Okay. And it says that from each of the TVT products, the hernia mesh product, and the suture, somebody from Exponent used a razor blade to cut about a one-centimeter-long section -- or sections of each sample. Do you see that?
A. I do.
Q. Okay. So is it fair to say that for each of these devices or products, one section was cut and

Page 40

prepared for these experiments, and a section of approximately one centimeter?
A. It says each sample that was cut was approximately one centimeter in length.
Q. Okay. So from each product --
A. Yep.
Q. -- for the QUV/UV oxidation experiment, how many pieces were cut to conduct that experiment of each of those products; the TVT, the hernia mesh, and the suture?
A. That were exposed to QUV?
Q. Yeah.
A. So I have one swath of material from Device 3859228. A second one, second swath of material from 3859228.
Q. What product is 389228 [sic]?
A. TVT device.
Q. Okay. And then it's --
MR. THOMAS: It's the lot number in the paragraph, Dan.
A. Yeah. And then there's a second mesh from that same lot, which we took out two swaths.
Q. And when you say "swaths", are you talking about the one-centimeter sample?

Page 41

A. That's right. A region of the mesh that was excised out. Each one of those swaths contains up -- on the upwards of 200 individual fibers.
And then we have two -- two swaths that were excised from TVT device, Lot No. 3832826. We have a swath excised from hernia mesh Lot No. 27770-20. And a second swath that was excised from that same mesh.
So -- and those would be the universe of QUV specimens.
Q. Okay. Did you -- I thought you did some QUV on the suture 6-0.
A. Right. I was just talking about mesh.
Q. Okay. Did you also do UV radiation on the PROLENE sutures?
A. Yes.
Q. How many swaths?
A. Appears to be 15 sutures.
Q. 15 sutures?
A. (Witness nods head.)
Q. Okay. And were -- so let me try to summarize how many samples were exposed to UV radiation on the QUV experiment.
As I understand it, there were four -- what you call swaths of the TVT.

Page 42

A. Correct.
Q. Correct? There were four swaths from the hernia.
A. I have six swaths from TVT and two additional ones from hernia.
Q. Okay. So six from TVT, two from hernia, and then 15 individual sutures?
A. I believe so.
Q. And based on your report, these samples were exposed to QUV radiation for a period of five to 12 days?
A. Correct.
Q. And then they were analyzed by you or somebody at Exponent using scan electron microscopy?
A. They were. Their surfaces -- surface topography and morphology was monitored through SEM.
Q. Okay. Who monitored the surface morphology?
A. Dr. Lyons.
Q. Okay. Who --
A. L-Y-O-N-S.
Q. Okay. So Dr. Lyons was conducting the SEM imaging or analysis during the QUV oxidation experiment.
A. Correct.

Page 43

Q. And after the five to 12 days, after the morphology or the cracking started to appear on the surface of the material, you did some additional analysis using FTIR?
A. Correct.
Q. And you did some additional SEM EX? Is that correct?
A. Correct.
Q. And then at some point some of these samples were submitted for histology preparation.
A. All of -- it's all from the same universe of specimens. So after they came out of the QUV chamber, a small section was excised off of one of the corners of the mesh, and that was analyzed through the FTIR technique that you just described. And the remainder of that specimen was sent off to histology.
Q. Okay. So how many samples were sent to histology?
A. All of them.
Q. Okay. So all -- so the six sutures -- I'm sorry. Strike that. The six TVT's, the two hernia samples, and the 15 sutures were sent to a third-party company called Histion?
A. Right. Which contained 7- to 800 individual fibers.
Q. Okay. And Histion was asked to do what?
A. They were asked to perform the staining portion of the work.
Q. And Histion is the same pathology company that you and Exponent used in the Mullins case?
A. Correct.
Q. Have you ever used Histion for any other work prior to Mullins?
A. I have not. Exponent has.
Q. How did you learn about Histion?
A. Through Dr. Garcia.
Q. So Dr. Garcia recommended to you Histion as the laboratory to conduct the processing and staining of -- of these samples. Is that correct?
A. Yes. I asked her to identify a lab that had this expertise, and that's the lab she mentioned.
Q. And how were the -- how did Histion -- strike that.
How many of the samples that we just discussed were sent to Histion for paraffin embedding?
A. Oh, it was roughly half. About half went into paraffin, and about half went into the resin.
Q. Is there a document that would identify for

Page 44

Page 45

me -- I don't need you --
A. Yeah.
Q. Just for later on, if I want to go and find out how many pieces of samples were embedded in paraffin by Histion, is there a document I can look to, to find that out?
A. If you look at all of the -- two things. You can look at the log. The log may contain that information. But if you look at the file names of all the micrographs, if you see a capital "P", that stands for paraffin. If you see an isolated capital "R", that stands for resin.
Q. Okay. So -- so roughly half of these samples were submitted -- or were embedded into paraffin by Histion. Right?
A. Correct.
Q. And what protocol did you instruct Histion to use in embedding these samples in paraffin?
A. The protocol that's listed in my report. So if you look at it on the thumb drive -- I know you don't have it. I'll just speak to -- speak to it, so it's on the record.
Q. I may -- I may have it. I have a protocol here. Is that what you're referring to?

A. I am.
MR. THOMAS: There's several protocols.
A. Yeah, there's several. But this one's entitled Histology, Embedding, and Staining Protocol for PROLENE Mesh and Sutures.
Q. You didn't -- when we -- when I took your deposition in Mullins, you didn't have any written protocols.
MR. THOMAS: Object to the form.
A. Sure, we did.
Q. You didn't produce any protocols.
A. These -- this staining protocol's in my report, in the Mullins report.
Q. Okay. Let's go ahead and mark as Exhibit No. --
(Discussion held off the record.)
(Recess held from 9:50 a.m. till 9:53 a.m.)
(MacLean Deposition Exhibit 16 - Histology, Embedding, and Staining Protocol for PROLENE Mesh and Sutures - marked for identification.)
BY MR. THORNBURGH:
Q. Okay, Doctor, I'm going to hand you what I've marked as Exhibit No. 16, which appears to be -- or is

labeled the Laboratory Protocol for Histology, Embedding, and Staining Protocol for PROLENE Mesh and Sutures.
(Discussion held off the record.)
Q. Doctor, do you recognize Exhibit 16?
A. I do.
Q. Okay. And is Exhibit 16 the written protocol for paraffin embedding and staining?
A. It is.
Q. Okay. And when was this protocol first written?
A. This particular document was written on January 19th, 2016.
Q. Okay. And that would have been after your Mullins deposition, correct?
A. This document, correct.
Q. Okay. So there wasn't an actual laboratory protocol like the one that we have here as Exhibit 16 that was written out by Exponent and produced to me in that litigation. Correct?
A. I disagree. Appendix A of my September 10th, 2015 report has histology protocols in it.
Q. There wasn't a formal Exponent document, correct?

MR. THOMAS: Object to form.
A. Our reports are formal.
Q. There wasn't a formal Exponent document protocol.
MR. THOMAS: Object to form.
Q. Other -- other than what was contained within your expert report. Right?
A. The expert report contains the protocol that we use.
Q. In any event, after I took your deposition in the Mullins case, this document, Exhibit No. 16, was created.
A. Correct.
Q. All right. And this is -- and the intent of this document is to have a protocol that can be followed by you or -- or individuals at Exponent so that you can follow the steps appropriately. Right?
A. That's what the protocol is used for.
Q. And it says -- under "Purpose", it says, "The purpose of this document is to describe histology, embedding, and staining procedures for PROLENE mesh and suture material."
Did I read that correctly?
A. You did.

Q. Okay. If you go down to Section C, it says "Paraffin-Embedding Protocol".
A. Yes.
Q. Okay. And it says -- under Section C, it says -- there's a -- well, strike that.
It says "Paraffin-Embedding Protocol", and there's a Footnote No. 1. Which if you go to the Footnote No. 1, it says, "Paraffin-embedded samples are prepared and stained following the protocol submitted by Dr. Iakovlev."
Did I read that correctly?
A. You read the footnote correctly.
Q. So what was the purpose of creating a paraffin-embedding protocol that would follow the protocol submitted by Dr. Iakovlev?
A. We were attempting to replicate his work on non-explanted mesh and PROLENE materials.
Q. Okay. So your goal was to attempt to reproduce the results of Dr. Iakovlev. Is that correct?
A. No, that's not correct. Not his results. We were just performing the control study which his experiments were missing.
Q. Okay. So it's your testimony that your

Page 50

purpose was to see if his study was reproducible --
A. No.
Q. -- in your control.
A. No. That's not what we tried to do. Mr. -- Dr. Iakovlev's experiment was on explanted materials. His experiments lacked a control in known oxidized material exposed to staining, and so we simply filled that gap. We didn't try to reproduce what he did. It was a fundamental step missing from his experiments that we filled with our control experiment.
Q. So it was important for your control experiment, since it's a control, to follow the protocol that was outlined by Dr. Iakovlev.
A. Correct.
Q. And who provided to you the protocol of Dr. Iakovlev?
A. I believe it came in some form from all the production documents. I don't remember where it came from.
Q. I didn't -- I looked through the materials that were produced, and I didn't see any written protocol of Dr. Iakovlev within the documents you produced. Maybe I'm missing it. I'm not suggesting that --

Page 51

A. Yeah. I don't -- I don't recall off the top of my head what production document that came from or where we found it, for that matter. I just don't recall.
Q. Do you know when you received it?
A. Well, we certainly had it before the first round of work. So sometime last summer, last fall.
Q. Okay.
A. He may have referenced something that was publicly available, and that's what we used. I just -- I just don't recall.
Q. Okay. But your -- your goal was to follow the same protocol that Dr. Iakovlev has -- had used. Right?
A. Yes. That was our intent; to basically do the same type of staining that he did; embedding and staining that he did.
Q. And if you don't follow the protocol of Dr. Iakovlev, your conclusions could be inaccurate.
MR. THOMAS: Object to form.
A. I think you'd have to show me what you mean by "different".
Q. If you didn't follow the protocol of Dr. Iakovlev, that could call into question your

Page 52

results.
MR. THOMAS: Object to form.
A. I'd need more information to pass judgment on that.
Q. Your intent was to follow Dr. Iakovlev's protocol.
MR. THOMAS: Object to form.
A. Our intent was to stain deliberately oxidized specimens from a well-accepted H&E process, correct.
Q. As a control.
A. As a control.
Q. And if you're doing a control, it's important for you to follow the procedures and protocol of Dr. Iakovlev.
MR. THOMAS: Object to form.
Q. Right?
A. We did a control experiment with H&E stains. That's what we did; oxidized specimens that were then ultimately stained with H&E.
(Witness asked for clarification by the reporter.)
A. We did an experiment with intentionally oxidized specimens that were ultimately H&E stained.
Q. Well, the purpose of a control is that you

Page 53

treat the control the same way that you treat the experimental material. Right?
A. Correct. We make every attempt to follow the procedure that was outlined in our protocol.
Q. And if you don't, you have an invalid control.
A. No, not necessarily.
MR. THOMAS: Object to form.
A. Not necessarily. You'll need to give me more information if you --
Q. I'm just trying to get some background information.
A. Asked and answered.
Q. Well, let's look at Exhibit -- let's look at Exhibit 16, Paraffin-Embedding Protocol. And you say that your -- you prepared this protocol following the protocol of Dr. Iakovlev. And then if you look at the very -- No. 1, it says you process and embed samples in an automated tissue processor according to the following schedule. Did I read that correctly?
A. I'm sorry, what page are you on?
Q. Page 1, Exhibit 16.
A. Um-hum.
Q. Section C.

Page 54

A. Yep.
Q. Where you are laying out the protocol for paraffin embedding. And you have a set of steps, right? 1 through 6?
A. Correct.
Q. And the first step is 70 percent reagent alcohol; number of changes, two; one hour each. Right?
A. Correct.
Q. Okay. And what was the purpose of doing that step?
A. Those are just dehydration steps.
Q. Now, there's no tissue, right?
A. There is no tissue.
Q. So there's no tissue on your samples. Right?
A. No. They're control specimens.
Q. Okay. So you're not really dehydrating tissue.
A. No, but we're following a standard embedding procedure. So we didn't want to leave any steps out.
Q. You didn't want to leave any steps out.
A. Correct.
Q. It's important to follow the steps.
A. Sure.
Q. Okay. If you go to Step 2, 80 percent

Page 55

reagent alcohol. Right?
A. Um-hum.
Q. What was the purpose of that? Additional dehydration?
A. Correct.
Q. And number of changes, one, for one hour.
A. Correct.
Q. Okay. If you go to Step 3, 95 percent reagent alcohol; number of changes, one, for another hour. Right?
A. Correct.
Q. And this is all going to be -- all these steps are going to be performed by Histion, right?
A. That's right.
Q. Exponent didn't have any role in performing these --
A. We oversaw --
Q. -- steps --
A. Excuse me. We oversaw the work.
Q. Step 4 is another dehydration. Right?
A. It is.
Q. Step 5, it says, "Xylene substitute (ProPar, Manufacturer)." What's that?
A. It's just part of the protocol. Xylene is a

Page 56

solvent that's part of the protocol.
Q. What was the purpose of using xylene in Step 4 -- or Step 5?
A. Probably just -- additional dehydration, if not alcohol removal, residual alcohol removal.
Q. Okay. And then Step 6 is the Lerica paraffin waxing; is that correct?
A. Leica, correct.
Q. Leica. And why did you have Leica here?
A. It's just the brand name.
Q. Okay. Is that the same brand that was used by Dr. Iakovlev?
A. I don't recall, and it wouldn't matter, because that paraffin goes away after you go through the entire process.
Q. Okay. So --
A. Just -- the paraffin's just used to hold the specimen in place during the microtoming.
Q. So, so far, your control, you've done dehydration, and then you've added some -- you've done the paraffin waxing. Right?
MR. THOMAS: Object to form.
A. In between there, there's the xylene substitute step. But, yes.

Page 57

Q. Okay. And you said that at some point the wax -- the paraffin wax gets removed through the steps in the protocol.
A. Correct.
Q. And that's important to remove the wax, right?
A. It's a by-product of the process. You're trying to -- you're ultimately trying to isolate the fibers. So, yes.
Q. What would happen if you didn't remove all the wax? Before you tried to stain.
A. I don't know, because we didn't have that issue. The paraffin was removed.
Q. You don't know what would -- or how the staining of your samples would be compromised if you didn't remove the wax?
A. I'm telling you I don't know because it didn't happen.
Q. I'm just -- I'm trying to understand. Do you have an understanding of the importance of removing the wax?
A. I don't know if I'd classify it as important. It just happens during the process.
Q. You don't --

Page 58

A. So if you think about it, the paraffin is on the outside of the fiber. We're staining a cross-section. Right? So the cross-section is not influenced or in contact with the paraffin itself. That's actually an encasement around the outside of the fiber. You would be staining a pristinely cut, if you will, cross-section which has no paraffin on it. So I don't -- I don't understand what you're getting at.

Q. Well, if the mesh was -- if the fibers were oxidized and cracked, right, that's not -- it's not cracked in the cross-section. It's cracked around the fibers on the outer layer.

A. Correct.

Q. Where the -- where the wax is going to be located. Right?

A. Right.

Q. Okay. So do you have an understanding of the importance of deparaffinizing these samples?

A. I have an understanding that the paraffin is removed from the process.

Q. How could the failure to remove the paraffin wax compromise the staining?

A. I would argue that it may not compromise the staining, because I have a freshly cut cross-section of

Page 59

all available material that has never been in contact with the pristine material, aside from what might have come in from the cracks. But I still have a layer of material that would not have been in contact, direct contact with the paraffin. So I don't understand your question.

Q. You're not a pathologist, are you?

A. I never said I was a pathologist.

Q. You don't hold yourself out as an expert in pathology. Right?

A. Correct. I do not study tissue.

Q. You don't know, sitting here right now, how a failure to deparaffinize these samples could compromise the staining in your study.

A. It won't compromise -- first of all, it didn't happen. And, second of all, it won't compromise my specimens for the reason I just described to you.

Q. It's your opinion that it wouldn't compromise the specimens if the paraffin wax is not adequately removed.

MR. THOMAS: Object to form.

A. Look, there is no evidence that there was insufficient removal of paraffin in our specimens. And what I'm telling you is the material that gets stained

Page 60

is a cross-section of the specimen. The paraffin is on the outside. So all of the cross-sectional area that we've now produced from the microtoming process is inboard from the paraffin.

Q. If you look at No. 2, it says, "Embed samples in paraffin blocks using Leica." Do you see that?

A. I do.

Q. And you go down through these sections until you get to Section D. Strike that.

"Trim the paraffin blocks, as necessary, and cut a 4-6 micron-thick sections [sic]."

"Briefly float the paraffin sections in a water bath set to 40-45 degrees Celsius to remove wrinkles and allow them to flatten."

Do you understand what the purpose of that step is?

A. Step No. 4?

Q. Yeah.

A. Yes.

Q. What is the purpose of that step?

A. To make it as flat as possible after floating in the water.

Q. Step 5 says, "Mount the sections onto adhesive-coated glass slides, then air dry for 30

Page 61

minutes and bake in a 45-50 degree oven overnight." Correct?

A. That's what it says.

Q. What is the purpose of that?

A. Just to drive off any excess moisture.

Q. The next section is a staining protocol for paraffin-embedded samples. Right?

A. Um-hum. Correct.

MR. THOMAS: Did you say standing?

MR. THORNBURGH: Staining.

Q. And so this is the section of the protocol where the mesh becomes stained. Right? Or the samples become stained.

A. Yes. There's -- there's some additional preparation steps to take on the staining, and then ultimately the staining, yes.

Q. Okay. And it says, "Stain samples using an automated stainer programmed with the following protocol."

A. Correct.

Q. Do you know what automated stainer program is used?

A. Not off the top of my head. It might be in the files somewhere.

Page 62

Q. In fact, if you were following Dr. Iakovlev's protocol, his protocol calls for manual staining. Correct?
A. Correct.
Q. All right. You did not follow manual-staining protocol.
A. No, we actually did. We ultimately chose to go manual in the second round.
Q. So you deviated from your protocol?
MR. THOMAS: Object to form.
A. We did. We determined that the automated stainer was a bit too aggressive and abusive, and we were -- we were losing some of the specimens during the staining process. So we felt like it would be -- because the specimens are so delicate, that it would be in our best interests to do hand-staining.
Q. How many of -- how many of your samples, the QUV -- yeah, UV-oxidized samples were -- went through the automatic or automated staining process?
A. In this round, none.
Q. And which round are you referring to?
A. The Wave 1 supplemental work. None of them went through the automated process.
Q. So the Mullins samples did?

Page 63

A. Correct.
Q. And you determined in Mullins that the automated stainer was too aggressive, and so it's your testimony that after Mullins, you decided to go from the automated staining to the manual staining.
A. Correct. And let me clear the record up on what I meant by "aggressive". The specimens just were not staying on the slides as well as we would have liked because of all the movement. And we just felt like a more delicate procedure by hand would allow us to maintain more specimens on the slides.
Q. Okay. So you testified in the Mullins litigation after you had already conducted the work.
A. Correct. Yes.
Q. You had already conducted the work, you had already experienced what you called the aggressive automatic staining. So you, before your deposition, already knew that automated staining would be inappropriate.
MR. THOMAS: Object to form of the question.
A. No. We would -- no, I would not characterize it as inappropriate. It was a discussion we had following -- just in follow-up to our Mullins work. I don't remember when it was. But we just said, hey,

Page 64

let's do manual staining next time.
Q. Okay. And so you decided to no longer do the automated staining.
A. Correct.
Q. And then you draft this protocol dated January 19th, 2016, after your deposition in Mullins, after the work that you performed in Mullins. And in your written protocol that was drafted after your experience with the automated staining, you write in your protocol that Histion needs to use an automated stainer.
A. Yes. But you're misinterpreting it. It's simply for efficiency and productivity. There's nothing wrong with either processes -- hold on. Let me answer my -- let me answer your question. There is nothing wrong with either one. We just wanted to be more efficient with how many survived the staining process.
There is nothing wrong or -- you don't get poor results from automatic staining. We just felt like we could be more efficient and have more slides survive the staining process if we did it manually. That's all. It was just a productivity discussion; no more, no less.

Page 65

Q. But what you're telling me doesn't make sense --
A. Sure it does.
Q. -- from -- chronologically. Okay? So in Mullins --
A. There's nothing chronological about it.
Q. Let me finish my question.
A. Go ahead.
Q. Okay? In the Mullins litigation, you performed some work using automated staining.
A. Correct.
Q. You determined that the automated staining was too aggressive to the samples.
MR. THOMAS: Object to form.
Q. Right?
A. It was not giving us the right amount of samples at the end of the day. Some of them were falling off.
Q. You decided in Mullins not to use the automated stainer anymore.
MR. THOMAS: Object to form.
A. Incorrect. Not during Mullins.
Q. Or after Mullins.
A. Sometime after Mullins, correct.

Page 66

Q. Then you or somebody drafts this written protocol after you've already gone through that experience, and you have written in here that the protocol needs to be done using an automated stainer.
A. All correct. It was simply a reflection -- before we started the second set of experiments -- excuse me -- second set of experiments, we reflected on what we learned from Mullins, and we said, hey, we don't get a high-enough yield using the automated stainer; let's just do it by hand; we think we can get more specimens to survive the process. That's it.
Q. Who performed the manual staining?
A. Histion.
Q. Who at Histion?
A. Simon Smith.
Q. Do you know Simon Smith?
A. I've met him.
Q. Is he a pathologist?
A. He has done staining for decades. I don't know his exact background.
Q. Do you know if he's a pathologist?
A. I just don't know.
Q. Have you worked with Simon Smith before?
A. We have.

Page 67

Q. You personally?
A. Yes. In -- for the Mullins work.
Q. But in the Mullins work, there was -- it was done by the automatic staining program.
A. Correct. But Simon was part of our effort. He was actually leading some of the effort inside the laboratory. You still have to do a lot of hands-on work to follow this protocol. So he was our -- basically, our main liaison, our main scientist there.
Q. Okay. So automatic staining -- when automatic staining is conducted, it's conducted automatically. You set the program; the machine does it itself.
A. To a large extent.
Q. So you take -- there's -- it's hands-free. Hands-off.
A. A portion of it is definitely hands-free.
Q. That's why it's called automated. Right?
A. That is correct.
Q. And so Histion was set up as a laboratory that routinely uses automated staining.
A. I can't -- I can't say it's routinely. They have an automatic stainer. They know how to use it. Is was employed during our Mullins work.

Page 68

Q. And then you deviated from that protocol, from the Mullins protocol, and -- and had Mr. Simon Smith, who's been using the automated staining program, you asked him to now use a manual staining program.
MR. THOMAS: Object to form.
A. He was the one that performed the manual staining, correct.
Q. Was he the same person in Mullins who set up the automated staining program?
A. He was.
Q. Do you know how comfortable Mr. Simon -- or Mr. Smith would have been going from what he performs in his laboratory, the automated -- automatic staining program to manual staining?
A. He didn't flinch.
Q. Do you know what his experience is with doing manual staining versus automatic staining?
A. Yes. He says he's done it all the time.
Q. Do you know -- personally, do you have any knowledge of what his experience is?
A. I can tell you that Histion has been staining products for 25 years, and they conform to the code of federal regulations in terms of their capabilities and report-outs.

Page 69

Q. How many years have they been using automated staining?
A. I don't know.
Q. You have no understanding, as you sit here today, how many times Mr. Smith had performed manual staining?
A. I don't have an exact number, no.
Q. You don't know, as you sit here today, what his skill level was for performing the manual staining.
A. I've already explained to you that this is a lab that's been doing staining for 25 years. He's an older gentleman with tremendous experience. I'd have no doubt in my mind that he did it correctly.
Q. Automated staining programs have been around for 20 years.
A. Show me a document that said that they've been around for 20 years.
MR. THOMAS: I'll have you mark as Exhibit No. 17 a document entitled Automation in IHC.
(MacLean Deposition Exhibit 17 - Document titled Automation in IHC - marked for identification.)
Q. So if you look at Exhibit 17 --
MR. THOMAS: Did you mean to give me your

Page 70

highlighted copy?
MR. THORNBURGH: No.
Q. What does "automation in IHC" mean?
A. Immunohistochemistry.
Q. Okay. And if you turn to the first page of Chapter 17 -- of Exhibit 17, Chapter 9.1, it says "History of IHC Automation".
MR. THOMAS: Is this from a textbook? Is there a title for the book, Dan, do we know?
MR. THORNBURGH: Automation in IHC.
MR. THOMAS: That's the chapter title. Do you know the book that it's from?
MR. THORNBURGH: I don't know the title. I don't.
MR. THOMAS: Okay. I'll just object to the question for that reason.
Q. "History of IHC Automation". "The first --" if you look at the first paragraph, about four lines up, "The first automated device capable of both IHC and in situ hybridization (ISH) was described in 1990."
A. I'm sorry, could you just tell me where you are, again.
Q. Page 1 under Chapter 9.1, first paragraph.
A. Um-hum. Yes.

Page 71

Q. Do you see there's -- see No. 4, about four lines up from the bottom.
A. I do.
Q. It says, "The first automated device capable of both IHC and in situ hybridization (ISH) was described in 1990." Right? Did I read that accurately?
A. You did.
Q. Okay. It says, "Automation quickly caught on." "Next Generation Sequencing into cancer diagnostics, and by 1995, there were several IHC instruments," (as read.) Right?
A. That's what it says.
Q. Okay. So the automation has been around for greater than 20 years.
MR. THOMAS: Object to form.
Q. Right?
A. Certainly the automation stated in this literature says that.
Q. Okay. And Histion was using automated staining in the Mullins case. Right?
A. Correct.
Q. And they have -- they have an automated staining program there. Right?

Page 72

A. Correct.
Q. Do you know how long it's been in place?
A. I do not.
Q. Do you know when the last time Mr. Simon [sic] conducted -- or performed manual staining on any sample before he met with you to work on the Wave 1 experiments?
A. No. But he assured us that he's quite capable and competent of doing manual staining.
Q. Were you there when he performed the staining?
A. I was not there on those days. And, by the way, just as a confirmation, that's why we do positive controls. So if you look at our rabbit tissue and all of the bovine serum which we have yet to talk about yet that's around some of the specimens, they all achieved staining.
So it's a moot point, in my opinion, because he clearly demonstrated that he has the capability and the expertise to do it, because all of our positive controls stained.
Q. Do you know if the automated system that he was accustomed to using and used in the Mullins case prior to this -- these experiments was an open or

Page 73

closed system?
A. I don't recall.
Q. So if we go back to the protocol, Exhibit 16, Section D where we were discussing earlier, where it says, "Stain samples using automated stainer programmed with the following protocol," that was a deviation. By going from automated to manual, that would have been a deviation of the protocol, right?
MR. THOMAS: Object to form.
A. We did not use an automated stainer.
Q. So it would have deviated from the written protocol.
MR. THOMAS: Object to form.
A. We chose to go with a manual staining for the reasons -- manual staining for the reasons I already talked about.
Q. And then if you look at the steps that were supposed to be programmed into the automated staining program, these steps would no longer be programmed, and now a human would be performing these steps. Right?
A. A human would be performing those steps, correct.
Q. Which part of this protocol describes deparaffinizing?

Page 74

A. These xylene steps, that's a solvent that's actually going to remove the paraffin.
Q. So Steps 19 and 20?
A. No. Much earlier on. Steps 2, 3, 4.
Q. Sorry. I didn't see those. And you had testified earlier that the deparaffinizing steps that were taken -- or that were used would have been sufficient for removing the paraffin wax?
A. Correct.
Q. What's your basis for that opinion?
A. The 25 years of experience that Histion touts. And also visual observations from the microscopy work.
Q. So it's not your personal experience. It's the fact that Histion has been around for 25 years?
MR. THOMAS: Object to the form of the question. He just said he's looked at it himself.
A. Exactly. It's two -- the answer is two-fold. One is the expertise and experience of Histion, having done this type of work for decades. And, two, it's the visual observation of the slides when they come out. You don't see any paraffin to the outside.
Q. So let's talk about touting the experience of

Page 75

Histion. Is Histion a laboratory that does diagnostic evaluation for patient clinically -- for patients clinically?
In other words, if someone gets a cancer, develops a cancer, or they have a tumor that gets removed by a surgeon, Histion is not the facility that would look at and determine whether or not a patient needs treatment, has cancer.
MR. THOMAS: Object to form.
Q. Right?
A. You're talking about histological examination of tissue. There are no tissues in my specimens. So I just don't understand the dots you're trying to connect here. There's -- we're not doing a tissue histological exam with my specimens.
Q. Histion is a pre-clinical laboratory.
A. That's correct.
Q. They're not a clinical laboratory.
A. It doesn't mean that they can't stain with expertise.
Q. Just answer my question. Okay? Histion is not a clinical laboratory. Correct?
A. They are not a clinical lab, correct. However, their data is good enough for the Government,

Page 76

for the Federal Government, because they do conform to the code of federal regulations with regard to their data.
So if someone comes to them for, say, pre-clinical experimentation, their data is accepted by the FDA.
Q. Move to strike, non-responsive. My question is very simple. Histion is not a clinical pathology laboratory. Correct?
A. Not according to their website.
Q. In other words, I'm correct. Right?
MR. THOMAS: Object to the form of the question.
Q. I just want to make sure the record's clear.
A. From what I have read, correct. You can ask them. They perhaps have done work that's not openly marketed on their website. I don't know. That's a question for them.
But in terms of the publicly available information, what you said was correct.
Q. Do you know what additional federal requirements are needed to run and maintain a clinical pathology laboratory?
A. Off the top of my head, no.

Page 77

Q. Are any of the individuals who are supervising and managing Histion, are any of those individuals pathologists?
A. I don't know.
Q. Do you believe that the steps that are outlined under Section D are the steps and the protocol that would have been used by Dr. Iakovlev?
A. What I can tell you is that we put what we believed was Dr. Iakovlev's protocol in front of the expertise and experts at Histion, and they developed something that we believed would be similar, if not identical, to what his steps were. That's how I can answer that.
Q. You, sitting here right now, you don't know whether or not the steps that are identified under Section D followed the protocol of Dr. Iakovlev.
MR. THOMAS: Object to form.
A. I believe we've made every attempt to follow what he did, based on the documentation that we have. And, again, our positive control specimens tell us that we achieved staining. I mean, that's what we're trying to do here. We're trying to see if oxidized material stains. Period.
Q. But were the slides charged or uncharged?

A. Charged.
Q. Were the -- how was the staining conducted? Was it a horizontal? Vertical?
A. Vertical.
Q. Vertical staining?
A. Correct.
Q. And you think that's consistent with the protocol outlined by Dr. Iakovlev?
A. I don't believe his protocol mentioned the orientation. But if you have a document that says otherwise, let me know.
(MacLean Deposition Exhibit 18 - Iakovlev Article on Degradation - marked for identification.)
Q. Marked as Exhibit No. 18 the publication from Dr. Iakovlev, Degradation of Polypropylene In Vivo, Microscopic Analysis of Mesh Explanted from Patients.
Have you seen that publication before, Dr. MacLean?
A. Yes.
Q. Okay. Do you see the section on Page 2 of Exhibit 18 called "Staining"?
A. I do.
Q. Okay. Do you see where Dr. Iakovlev explains

the types of staining that he conducted in his studies?
A. (No response.)
Q. At the very beginning. He did H&E staining, and he did additional staining using trichrome, Von Kossa, and some -- do you see where I'm at?
A. I do. I see the paragraph, bottom right-hand corner on Page 2. I believe that's what you're referring to.
Q. Okay. You only did H&E staining, right?
A. Correct.
Q. You didn't do the Von Kossa staining. You did not perform the trichrome staining. Right?
A. We did not.
Q. You did not perform the immunoparaffinized staining using immunoperoxidase, right?
A. I did not.
Q. Okay. If you turn to Page 3, see the "New Mesh Control"? Do you see where I'm at?
A. I do.
Q. "Portions of pristine trans --" and this is the protocol that Dr. Iakovlev uses.
A. In -- in this publication.
Q. Okay. It says, "Portions of pristine transvaginal sling devices of three different

manufacturers were placed in 10 percent buffered formalin." Right? "The mesh was then sampled for light microscopy at two weeks and one, two, and four months in two separate experiments."
Did I read that correctly?
A. You did.
Q. Okay. "Tissue processing; embedding, sectioning," says, "Charged coated slides." Do you see that?
A. I do.
Q. And then it says, "And staining (manual and [sic] horizontal tray) were carried out."
Did I read that correctly?
A. It says "manual on horizontal tray".
Q. Um-hum.
A. Correct.
Q. Okay. So Dr. Iakovlev's staining was conducted manually on a horizontal tray.
A. In this publication.
Q. Okay. And the staining that was conducted by Histion would have been -- in Mullins, it would have been automated. Right?
A. In Mullins, correct.
Q. In the Wave 1 cases, it was, according to

you, it was done manually on a vertical tray -- vertical standing.
A. Correct.
Q. So it was not horizontal.
A. Ours was not horizontal.
Q. Okay. And, by the way, where -- in all of your materials that you've produced, where did you -- where did you record the fact that the protocol wasn't followed; that the -- your written protocol, Exponent's written protocol was deviated from by going from automated staining to manual staining?
(Discussion held off the record.)
A. Do you have a full copy of my supplemental report? Is that what you handed me?
Q. That's what I handed you.
A. If you look on Page 37 of the supplemental report, it is documented. I'm sorry. Page 36 and 37. Item 6 on Page 36 reads, "Paraffin-embedded samples were stained by hand using the following protocol." And, likewise, a similar comment is on Page 37 by the number four for the resin-embedded samples.
Q. Do you know what the -- why some pathologists would use vertical staining versus horizontal staining?
A. The only thing I can tell you, that in the

Page 82

discussions that we've had with Histion, vertical staining -- vertical orientation is preferred, because it ensures that you get good rinsing, and the rinse actually moves away from the specimen. The slide, I should say. So it was just -- it's a preferred method by Histion. They feel that they get a better wash from that -- from that technique.

Q. And what do you mean by a "better wash"?

A. Well, the -- the slides are vertically oriented, so gravity actually pulls or drops the wash solution down over the sides of the slides and then down away from the slides. So rinsing and washing is facilitated by that orientation.

Q. You agree with -- would agree with me that the protocol that was used by Dr. Iakovlev, at least as to the positioning of the slides as they're stained, was different from that used by Histion.

MR. THOMAS: Object to the form of the question.

A. Only with respect to his publication. Can you show me in his reports for any of these matters where he's cited horizontal orientation?

Q. Did you believe, when you endeavored to conduct these experiments and follow the protocol of

Page 83

Dr. Iakovlev, that Dr. Iakovlev performed the staining vertically, rather than horizontally?

A. We had no indication. From -- per reading his reports.

Q. Did you attempt to look at Dr. Iakovlev's publications to determine what protocols Dr. Iakovlev used?

A. We certainly referenced them.

Q. All right. And you would agree with me that the protocol that Dr. Iakovlev used was different than the protocol that you used, at least with respect to the positioning of the slides when they were stained.

A. Show me --

MR. THOMAS: Object to the form of the question.

A. Show me the protocol in any of -- in his reports that cite horizontal orientation that I would have made that determination from. From his reports, not a publication.

Q. Listen to my question.

A. Okay.

Q. Okay? I mean, your goal was to follow the protocol outlined by Dr. Iakovlev.

A. To the best of our ability, correct.

Page 84

Q. And my question to you was: Based on your review of the publication, Exhibit No. 18, of Dr. Iakovlev, you'd agree with me that the positioning of the slides for staining purposes was different.

MR. THOMAS: Object to form.

Q. Than the positioning used by Dr. -- by Histion.

MR. THOMAS: Same objection.

A. Only in that publication. Not in his reports with respect to any of these litigation matters.

Q. Do you have any basis to believe or to testify that Dr. Iakovlev used any other protocol other than that used and reported in Exhibit 18, his publication on degradation?

A. We have no basis either way. It's not -- there's no written protocol assigned with his report -- associated with his reports that tell us either way.

Q. Well, you said that your goal was to follow the protocol of Dr. Iakovlev.

A. To the best of our ability, based on what he submitted for expert reports.

Q. You didn't follow the protocol --

A. Is that --

Q. -- of Dr. Iakovlev --

Page 85

A. -- an expert report?

MR. THOMAS: One at a time.

Q. -- as described in Dr. Iakovlev's publication concerning the degradation of explanted PROLENE mesh?

MR. THOMAS: Object to form of the question.

A. In a non-expert report, correct.

(Discussion held off the record.)

(Recess held from 10:45 a.m. till 10:51 a.m.)

BY MR. THOMAS:

Q. Okay, Dr. MacLean, why did you decide to only use H&E staining and not the other staining that Dr. Iakovlev has used?

A. Because I think when you look at his reports, he certainly suggests that the staining that's taking place in his cracked bark is H&E. I know that there are other stains that he used, but the one that we chose to focus on was H&E.

Q. Did you ever try to use any of the other stains?

A. We did not.

Q. If you'd turn to Page 5 of Exhibit No. 18, which is Dr. Iakovlev's publication.

A. One more time. Figure or page?

Q. Page 5, Figure 4.
A. Okay. I am there.
Q. Do you see where in Figure 4 there's different staining that was discussed that was done by Dr. Iakovlev?
A. (No response.)
Q. If you look at -- on Image (a) on Figure 4 --
A. Correct.
Q. -- Von Kossa staining -- do you see that -- was negative for calcium in the brittle bark?
A. That's what it says, correct.
Q. Says, (b), "Trichrome stain shows that the deeper parts of the bark have smaller staining porosity (red) than those close to the surface (green) which correlates with TEM," transmission electron microscopy, "findings." Do you see that?
A. Yes, that's what it says under (b), yes.
Q. Okay. You didn't use trichrome, right?
A. We did not.
Q. Okay. And do you have any opinions about why in (b), why trichrome would be able to be trapped within the degraded -- what we allege to be the degraded layer of the PROLENE fibers?
MR. THOMAS: Object to form of the question.

A. I have no opinion on that.
Q. You're not going to offer any opinions at the -- at any trial concerning the additional findings of Dr. Iakovlev that are discussed in his publication, in his expert report, and here in Figure 4?
MR. THOMAS: Object to form of the question. That's much too broad.
A. I don't have any opinions at this time on Von Kossa staining of the crust layer.
Q. And you don't have any opinions regarding Von Kossa stainer -- staining of the outer layer of the mesh because you didn't conduct any of those studies. Right?
A. I have not conducted any Von Kossa staining studies.
Q. Okay. And you don't -- and won't offer any opinions concerning Dr. Iakovlev's trichrome staining and his findings related to the trichrome.
MR. THOMAS: Object to form of the question.
A. Well, I -- I don't know. I don't know. But at this point in time I can tell you this: That his discussion on the trichrome stain simply talks about porosity that may exist in that crust. It does nothing to characterize that material in terms of whether it's

PROLENE or some other material. It's just talking about the relative size of alleged pores that are on either side of the bark.
So to the extent that he uses that technique to determine that it's PROLENE, I would have an opinion. But if he's just using it to talk about porosity and porosity alone, then I wouldn't have an opinion.
Q. Would you -- would it be significant to you at all if Dr. Iakovlev conducted additional staining to determine whether or not the outer layer was proteinaceous; used a stain to look for protein, and the outer layer didn't stain?
MR. THOMAS: Object to form of the question.
Q. Would it be significant, in your opinion, as an expert here, whether or not Dr. Iakovlev had actually done some testing, staining that would identify whether or not that outer layer is protein?
MR. THOMAS: Object to form of the question.
A. Well, he's already done some of that work today. We know that there's a biological component to this crust layer, because it takes on H&E staining. So I guess I'm missing your point.
Q. Well, if you -- well, Dr. Iakovlev's

opinion's different than yours, right? Dr. Iakovlev's opinion is that the degraded polypropylene layer traps H&E, which is different than your opinion. We can agree that you have different opinions, right?
A. We have -- sure, we can agree on different opinions.
Q. Okay. But did you -- would it be important to you if Dr. Iakovlev had done additional protein staining and found that the outer layer did not stain?
MR. THOMAS: Object to form of the question.
A. I -- I would need to see that research. I'd need to see that study.
Q. Well, if you look at Page 5 of his publication, Exhibit 18.
A. (Witness complies.)
Q. "Immunohistochemical stain for immunoglobulin G (IgG stained brown)." Do you see that? "IgG," immunoglobulin, "is present in almost all human tissues and fluids. It is deposited on the surfaces of degraded polypropylene, but it is not mixed within it."
Do you see -- do you see Figure C?
A. I do. And I think you're reading the text that corresponds to Figure C. Is that correct?
Q. Okay. So do you see Figure C, that when

Page 90

immunoglobulin staining was conducted, immunoglobulin staining only stains protein brown. Right?
A. Well, that's what he says, but I haven't done my own research to verify that.
Q. You don't know one way or the other.
A. No, but I could certainly find out.
Q. Okay. But sitting here today, because you're not a pathologist, you don't know one way or the other whether or not immunoglobulin would stain brown in the presence of tissue or fluids.
A. No. But I know --
Q. Protein.
A. No. But I know that H&E stains biological materials. And there's no biological component to native PROLENE.
Q. Do you understand that immunoglobulin is found within the tissues and the fluids of the human body?
A. I can only recite what's written here.
Q. Do you understand that immunoglobulin is found within protein?
MR. THOMAS: Object to form of the question.
A. It's the same answer.
Q. Okay. So do you agree that based on the

Page 91

staining done, as depicted in Figure (c) of -- Image (c) of Figure 4, it didn't stain brown?
MR. THOMAS: Object to form of the question.
A. (No response.)
Q. There is no immunoglobulin within the cracked layer of the PROLENE.
MR. THOMAS: Object to the form of the question.
A. I am -- I am going to leave the interpretation of these figures up to Dr. Iakovlev. These are not my figures, this is not my work.
Q. Okay. So you defer to Dr. Iakovlev in that --
MR. THOMAS: Object to form of the question.
A. I'm not -- I'm not deferring to him. I would say he needs to be asked those questions, not me.
Q. Okay. You're not going to offer any opinions at trial concerning the images contained within Figure 4.
A. Not at this time.
Q. Okay. And you're not going to be offering any criticisms of Dr. Iakovlev containing -- concerning any of his other opinions as they relate to other histopathological staining that he conducted.

Page 92

MR. THOMAS: Object to form of the question.
A. If it's -- could you -- I need to hear that question again.
(Read back by the reporter.)
A. I think it depends on the question I'm going to get asked. Because, like I just mentioned, going back to the trichrome stain, he hasn't used that technique to verify that the cracked layer is PROLENE.
So it really is going to come down to what questions I'm asked and -- and how it relates to my polymer science background. That's -- that's how I'll answer that.
Q. So you're saying that the trichrome staining that was conducted by Dr. Iakovlev doesn't determine whether or not the cracked outer layer is -- is PROLENE?
A. What I'm saying is the only thing that he's mentioning with respect to trichrome stain is the presence of some alleged set of pores that vary in size. He's not using it as a technique to confirm that the cracked layer is PROLENE or oxidized PROLENE. He's simply making a statement about some, in his opinion, inherent pore size within that layer. We -- he still hasn't identified what that material is within that

Page 93

layer.
In other words, I could have a crust or a cracked layer on the outside of Material X that has nothing to do with PROLENE, and it can still have pores in it.
Q. You've seen some of the other work done by Dr. Iakovlev, where he uses polarized light to identify -- to identify polypropylene. Right?
MR. THOMAS: Object to form of the question.
A. No. He has not. He has identified a material that illuminates. But polarized light by itself does not tell you that the material it's illuminating is PROLENE.
Q. Are you going --
A. It just -- it just tells you that you have a material that has some degree of molecular order to it. That's it.
Q. Are you going to offer any opinions at trial that tissue or protein -- proteinaceous material is birefringent when reviewed under polarized light microscopy?
A. We may. There's certainly evidence of that in some of his micrographs. We see that collagen will actually illuminate to a certain degree under polarized

Page 94

light.
Q. Okay. Have you looked at -- have you conducted any polarized light experiment to determine whether or not protein is birefringent?
A. (No response.)
Q. Under polarized light?
A. (No response.)
Q. You didn't conduct any separate experiment concerning whether or not protein is birefringent, right, using polarized light?
MR. THOMAS: He's looking right now.
Q. Maybe I can speed things up --
A. Hold on. I apologize for the delay. It depends on the degree of cross-polarization. There are certainly some images -- and, again, this will be all in the files that you have -- where if you look at serum and then some degree of magnification and then H&E, which means it's been stained, cross-polarization, XPOL, there are certainly several images that are viewed under polarized light that show the serum proteins; that they're illuminated in those micrographs.
So there is some degree of illumination of a proteinaceous material in my vials. I can show you an

Page 95

image, if that helps.
Q. You were just reading -- let me see what you're looking at.
A. (Witness indicates.) And the file name is in the top left-hand corner, if you want me to read that into the record.
Q. Yes, read -- it's at 15791_serum_R_63XH&EXPOL_03-imageexport-29? Is that the file?
A. Correct.
Q. And who took that image?
A. It would be -- Dr. Benight took this image for me.
Q. And what is that image of?
A. This is a microtome sample of a mesh that was put through the protocols that we've talked about, but it includes the presence of bovine serum on the outside of the mesh.
Q. Okay. So you say that that -- the bovine serum experiment you conducted went through the same protocol as the -- as outlined in the paraffin embedding?
A. Correct.
Q. And then it was polarized -- or analyzed

Page 96

looking at -- with polarized light?
A. Correct.
Q. And that was done by Dr. Benight?
A. Correct.
Q. And it's your testimony that the bovine serum experiment demonstrated that bovine serum protein is to some degree birefringent?
A. It illuminates under polarized light.
Q. Okay. And was the -- that was -- in the bovine serum experiments, those samples weren't oxidized. Right?
A. Correct.
Q. If you look at -- if you turn to Figure 18 of your report.
MR. THOMAS: Which one? The supplemental?
MR. THORNBURGH: The supplemental report.
MR. THOMAS: Page 27?
MR. THORNBURGH: Yeah.
Q. I'm sorry, Page 28, Figure 19. Supplemental report, Exhibit 15. You have some images of the UV-oxidized or QUV-oxidized PROLENE fibers?
A. (No response.)
Q. Are you there?
A. Yes, I am.

Page 97

Q. Okay. And you write that, "Fibers with several cracks embedded in paraffin. No staining is evident. Mesh fibers are shown under bright field light, (a) and (b), and illuminated under cross-polarized light, (c)."
And the cracking that you describe here in these figures -- let me ask you this question: Do you know what "chatter" is?
A. In a general sense I know what chatter is. Maybe -- maybe you can help me define it.
Q. In the pathology field, field of pathology and microtoming, do you know what "chatter" is?
A. I don't know if I've heard it expressed as the term "chatter", but perhaps you're talking about the blade chattering as it comes across the cross-section? Am I correct? Is that what you're --
Q. Right.
A. -- describing?
Q. Right. So you -- when the microtome blade isn't sharp enough, it can create chatter, right, where it comes across the fiber during the cross-section and cracks it -- the material up.
A. I understand what you mean by "chatter". I'm not going to agree with the whole notion that it

Page 98

necessarily cracks things up. But go ahead and ask your question.

Q. Okay. What do -- well, I need to know what your basis is for -- so let me just -- if you look at Figure 19, (b) and (c), you describe this as cracks caused by the UV oxidation.

A. You bet.

Q. Okay. And have you ever seen chatter under a microscope?

A. I've certainly seen on occasion some artifacts on a microtome surface that might be related to the movement of the blade.

Q. Has anybody ever trained you on how to identify artifact caused by chatter?

A. I don't know if anyone has formally trained me, but I've been doing microtoming for 20 years, and I understand the general phenomenon that you're describing.

Q. And in Figure (d) and (c), you don't believe those -- that cracking that's demonstrated on these images is actually chatter, rather than cracks caused by the oxidation of PROLENE?

A. Here's what I can tell you: These samples are definitively cracked, because if you look at the

Page 99

pre-microtomed micrographs, all of these specimens are riddled with cracks.

And, more importantly, when we went from the whole fiber specimen down to the microtoming, we actually denoted where we were going to do the microtoming so that our microtomes would align with known cracks from the oxidation process.

So there's zero doubt in my mind that cracks that are that are shown on these images are a result of UV oxidation.

And -- and just let me add to that. We've done the FTIR work to confirm oxidation was achieved.

Q. The cracking that you observed in the UV-treated specimens, did that cracking penetrate through the entire fiber, or did it only go to a certain depth?

A. It depends. I think for some of the PROLENE fibers -- sutures, rather, we got some pretty significant cracking and damage throughout -- I'll call it the bulk of the suture.

In the mesh, I would say more of it was around the perimeter, like we've seen before. Similar to what we saw in the microstaining -- in the microscopy work last fall.

Page 100

Q. In Figure 19 (b) and (d), are those images of the mesh fibers or the suture fiber?

A. Those are mesh fibers. And I'm just going to correct the record. That's (b) as in boy, (c) as in Charlie.

Q. Correct. Did you identify -- strike that.

Who took the images, the microscopy images?

A. Dr. Benight, with some assistance from Dr. Garcia.

Q. Okay. And prior to her involvement in this litigation, had she ever taken -- had she -- strike that.

Prior to her involvement in this litigation, had she ever done microscopy imaging before?

A. I'm sure she has, but I have to -- I would either defer to her CV or whatever she's testified to.

Q. Do you know whether or not she's ever done microscopy before?

MR. THOMAS: Microscopy or --

Q. Microscopy imaging.

A. I can certainly look it up. She might reference it on her CV.

Q. I only say this because I -- you know, when I looked at the materials that were produced yesterday,

Page 101

the microscopy images and the microscopy that was produced in the Mullins case, those images were very blurry.

MR. THOMAS: Which ones?

MR. THORNBURGH: Virtually all of them.

Q. I mean, you've seen them, right?

A. I have seen them.

Q. They're pretty poor images. Right?

A. I would -- I would argue that it was still clear enough to discern what was stained and not stained. But we certainly attempted to improve on our microscopy this time around, in terms of their visual clarity.

Q. Okay. The visual clarity, even this time around, wasn't very good, were they?

MR. THOMAS: Object to form.

A. No, I disagree. They're fine. I think that they're very good.

Q. Well, turn to Page 25.

A. (Witness complies.) Okay.

Q. I'm just going to use this as an example. 25 of your report, there's a Figure 15. Blurry image, right?

A. Only a portion that's in a different focal

Page 102

plane is blurry.
Q. There's a -- the focal point in the right and left of this image is blurry.
MR. THOMAS: Object to form.
A. There is some discreet regions that are blurry, but it's -- it's not because of the microscope, it's not because of the user. It's because of the focal plane that you're focusing in on.
Not -- like we talked about six months ago, not all these specimens are perfectly flat. There's going to be some slight variability. And you're at the micron level. So when you're zoomed in this close on a specimen that's not ideally flat, you're going to be in different focal planes. It's inevitable.
Q. If you look at (b), it's also blurry.
MR. THOMAS: Object to form.
A. I'm sorry; which one?
Q. Figure 15, Image (b) is blurry.
MR. THOMAS: Object to form.
A. No. Not -- no. Not every region is blurry. There are certainly some areas -- there are certainly some areas that are not blurry.
Q. Turn to 26.
A. (Witness complies.) All three of these

Page 103

images are blurred out.
MR. THOMAS: Object to form.
Q. Right?
A. I disagree. There are certainly discreet regions that are in focus, and that's what we would expect.
Q. Do you -- you see on Page 26, the bottom image, is there any area on that image that isn't blurry?
A. I'm going to look at the native image, because I don't think that's a fair indication of what's blurry and what's not blurry with that size micrograph inside to record it.
Q. While you're looking at it, did you ever go back and talk to Miss Benight and ask her if she could take some better images?
A. No. I was happy with the images that she made.
Q. You were happy with the images that Dr. Benight provided to you?
A. Yeah. Not every -- at this magnification, this sample size, not every single one of them is going to be a perfect picture, if you will. It's just not -- it's just not realistic.

Page 104

Q. Can you point out for me on any of these images where the degraded -- on these microphotographs, where the degraded outer layer of the PROLENE fiber begins and ends?
MR. THOMAS: On which images are you talking about?
A. Yeah, which images?
Q. On any image in your report.
A. Well, for the -- for the chemically oxidized, it would be all of the exterior surfaces, because they've all seen the same chemical environment.
So when we confirmed through our spectroscopy that oxidation was achieved, it would be all of the surfaces. It wouldn't be just in the discreet regions.
That -- I'm giving you that answer because we -- the last thing we were on was on Page 26.
Q. I'm just trying to understand this. In the images I look at, I don't see the degraded outer layer.
A. Be more specific. In what?
Q. I don't see a degraded, cracked outer layer on any of these microphotographs that you've provided.
MR. THOMAS: Anywhere in the report?
A. Did you look at the SEM images? They're -- they're riddled with cracks.

Page 105

Q. Well, but the SEM images are a different image. Right?
A. No. What I'm explaining to you is when the SEM -- when the individual fibers were cracked, we mounted those specimens on a mounting board, and we actually noted, look, here's a specific crack, let's microtome right through this cracked region. So, in essence, this one-to-one correlation between SEM cracking and the cracks that are -- the cracking that's exhibited around some of the QUV specimens that we talked about.
Q. You'd expect that if you took a -- what you called an intentionally oxidized PROLENE sample --
A. Which method?
Q. Using QUV.
A. Okay.
Q. -- and you looked at it under the standing electron microscopy, and you saw the severe cracking that some of your images have demonstrated --
A. Correct.
Q. -- then you'd take that same material, and you do, you know, embedding and microtoming and do a cross-section --
A. And I --

Page 106

Q. -- and put it under a microscope --
A. Sure.
Q. -- you expect to see that outer degraded layer in the microphotograph. Right?
A. Yeah, and we -- and we do. It's on 6 -- it's on 19 (b). I mean, the cracking that's at -- if I use that mesh cross-section as a clock, you know, certainly the cracking that we see at 9:00, 10:00, 11:00, I am a hundred percent convinced that that is from UV oxidation.
Q. You think that's from UV oxidation and not chatter.
A. I do.
Q. Okay.
A. Again, that's for two reasons. One, we've confirmed it through FTIR. That's -- there's certainty there. And then, two, we've got it connected back to the SEM microcracks.
Q. So how do I connect Figure (b) and (c) -- which are the same image, right? Same fiber, right?
A. Yes.
Q. How do I track backwards this figure to a scanning electron microscopy and then to FTIR?
A. It's all in the files that we've given you.

Page 107

All of -- all of that one-to-one correspondence exists. If you can -- if and when you can find these images on the information we've given you, you find that image, and you trace it back to the overall bulk swath specimens that we've talked about, you will see how they are mounted, you will see the location that we chose to microtome from. It's all there.
Q. This image on Figure 19, is this the best image that you had of an intentionally oxidized PROLENE sample?
MR. THOMAS: Object to form.
Q. For microphotograph --
A. I don't know --
Q. -- imaging?
A. I don't know if it's the best. It's certainly a representative fiber that suffered from UV oxidation.
Q. And the image is blurry, right?
A. No. I don't think the image is blurry.
Q. You don't think the image is blurry?
A. No. Can you not see the cracking at 9:00, 10:00, 11:00? Can you not see that? Because I --
Q. I see some cracking, but it looks like -- that looks like chatter to me.

Page 108

A. Okay. It doesn't look like chatter to me. And -- and the chatter -- we know it's not chatter because of the reasons that I just walked you through.
Q. Is this sample -- has this sample been preserved?
A. Sure. Yes.
Q. And where is it being preserved at?
A. In Menlo Park.
Q. Are all the samples preserved at -- where did you say?
A. Menlo Park. That's our -- that's where Dr. Benight and Dr. Garcia work from.
Q. Menlo Park is --
A. That's two words; Menlo Park in California.
Q. California.
A. (Witness nods head.)
Q. Did you look at any of these images yourself under a microscope?
A. We may have done some video sharing at some point to get some realtime microscopy across the country. I've also looked at all of the ones from the Mullins work first-hand.
Q. You have some additional -- so the only ones that you looked at first-hand were for Mullins. You

Page 109

didn't look at any of these --
MR. THOMAS: Object to form.
A. I've looked at all of those.
Q. Through the microphotographed images that were sent to you from Dr. Benight.
A. Yeah. And/or a -- some sort of video session that we might have set up at some point in time.
Q. On Page 30 -- or, actually, Page 31, you talk about polarizing artifact.
A. Yes.
Q. And here you are -- I think what you're doing is you're attempting to demonstrate what you believe the -- it's your opinion that the cracked outer layer that is identified by Dr. Iakovlev is artifact from polarized light microscopy?
A. Oh, no. Not necessarily. It's -- this is just a caution and a warning that when you use polarized lighting, that you can get some degree of shading and some -- and varying degrees of illumination, and you just need to be aware of those artifacts as you interpret the results.
Q. Are you going to offer any opinion at trial that any of the photo -- or the microphotographs that you've looked at that were taken by Dr. Iakovlev were

Page 110

caused by polarizing artifact?
A. I don't know. I'd have to go back and look at his universe of images. All I'm saying here is that when you use polarized light, you just need to be careful, because you could introduce things that just truly aren't there. That's -- that's all I'm saying.
MR. THOMAS: And just so you know, just in case you don't know, there are two videos in the information --
MR. THORNBURGH: I've seen those.
MR. THOMAS: Okay.
MR. THORNBURGH: I've seen those.
MR. THOMAS: That's fine.
Q. Are you offering -- are you -- have -- sitting here right now, do you have any opinion that any of the microphotographs that were taken from -- by Dr. Iakovlev and are in his expert report are actually depicting some sort of polarizing artifact?
MR. THOMAS: Object to form.
A. I can say this: That there may be polarizing artifacts in his images. If you're asking me if I believe that the crust that we've all been talking about for a very long time is an artifact of polarized light, the answer's no.

Page 111

Q. Okay. And you've seen that in the degraded -- what we call the degraded crust or degraded bark, that Dr. Iakovlev has found that within that cracked layer, there are blue granules caused from the placement of those dye or the pigments during the manufacturing by the Defendant. Right?
A. I --
Q. So, in other words, the Defendant uses a -- blue granules or blue pigments to -- to color their fibers blue. Right?
A. Correct.
Q. And in the cracked outer layer of the mesh that Dr. Iakovlev has looked at, in that cracked layer, there are blue pigments or blue granules. Okay?
MR. THOMAS: Object to the form of the question.
A. I think that is his interpretation of what he sees.
Q. What is your interpretation of what is shown in the microphotographs of Dr. Iakovlev?
A. I think I -- I see two discreet layers, and I can show you an image that will help tease that out.
So if you look at Dr. Iakovlev's Wave 1 report, Page 94. I'm in Figure 13(k), as in Karen, and

Page 112

I'm in specifically Image (c) as in Charlie.
Q. Okay.
A. Are you with me?
Q. Yeah, I'm there.
A. So in that particular image, I clearly see a stained region that's just in -- I'll call it inboard from the white reference arrow, and then a defined boundary between -- there's no staining in the blue particles.
So, to me, this is a clear indication that the crust is something else, for two reasons: There's no blue granules in the purple swath of material that you see there, is a discreet boundary, and, likewise, there's no staining in and around the blue dyes, the blue particles.
So I -- I see it very differently than he does.
Q. So let me ask you this question: Do you know -- do you have any understanding as to whether or not those blue granules will also oxidize and degrade over time?
A. The blue granules --
Q. Um-hum.
A. -- themselves?

Page 113

Q. Right.
A. I haven't thought about that enough. I would have to think about that before I give you an answer.
Q. Okay. Because if they did, it would make sense that towards the surface, where the highest activity of oxidation is occurring of the fibers, that you'd expect to see a decrease in the blue fibers at that level.
A. Well, fine. Let's continue that logic, then. What is the answer as to why the inner boundary didn't stain?
Q. Where are you looking at?
A. I'm just looking to the left -- let me just point it out to you so we're all on the same page.
Q. Well, let me just -- let's just do this real quick.
A. Sure.
Q. We're running out of time.
A. Okay.
Q. Let's look at Exhibit No. -- or Image No. (d) of Figure -- of this figure set. Okay? On Page 94. Do you see (d)?
A. I see (d).
Q. Okay. Do you see the detached degraded --

Page 114

what we have allege to be degraded bark?
A. I do.
MR. THOMAS: Object to form of the question.
Q. Do you see the blue granules throughout that degraded layer?
A. I do.
MR. THOMAS: Object to form.
Q. Okay. And what is your explanation for the degradation and the presence of the blue granules in this image?
A. Well, because what you can have on a biased-cut specimen, you can actually have two layers of material. And you're only looking at a one-dimensional image here.
So if this has, say, a portion -- and I talked about this in one of my reports. Because of the bias cutting, I can have the crust layer on top, if you will, and then some of the residual PROLENE on the bottom of that same specimen. And so when I look at it top down, I'm actually looking through both simultaneously.
Q. So what evidence do you have that you're looking at a crust layer that is on top of a polypropylene layer causing this image to look the way

Page 115

it does?
A. You can actually just show it through basic geometry. If you cut a basic -- excuse me. If you have a bias-cut fiber, you can actually just show it through simple geometry, that you can have this -- what I'll call a compounding effect; one material on top of the other around the perimeter.
Q. Is that what you were attempting to do in your supplemental report on Page 31?
A. No. No. 31 was just talking about artifacts that come up from the -- that come about from the polarization process or the polarized light illumination.
Q. On Page 30? Is that what you're referring to?
A. Yeah, to some extent. I mean, this is just showing how you can have this bias cut that we talked about.
So if you look at Image (b) -- Figure 21, Image (b), you can -- none of these specimen, when you microtome them, you don't -- you aren't guaranteed a perfect circle. Is that clear? Does that make sense? Because of the fact that the mesh is a three-dimensional knit. And so when I microtome up

Page 116

across some sort of arbitrary plane, I'm also going to have some degree of bias cutting.
And what I'm saying is that, yes, if I have a bias cut and now I place it on a slide, I may have the notion of two materials, one which is PROLENE, and one which is the crust in the same field of view looking top down.
Q. There's no evidence in -- on Page 94 of Dr. Iakovlev's report, Image (d), of a bias view or bias cut.
A. We can't tell here. You need to actually look at the entire cross-section father away to know whether you've got a perfect circle or some sort of bias. You just can't tell.
Q. Because I think the way you've described it is that if you have a biased cut, where it's not a totally flat cross-section, then at -- then the crust could look as if it has blue granules in it, but it's really an artifact caused by the core.
A. Not necessarily the core. It could be any residual PROLENE that's sitting just below the crust itself. So it doesn't have to be the core. I know why you're asking that, because (d) has no core in it. You don't have to have the core.

Page 117

It's just a matter of that -- that banded crust material coming from a bias cut could -- could be two different materials, one on top of the other. And you're making -- you're getting an illusion of the blue dyes and the blue granules being inside of the crust.
Q. So you think -- it's your opinion, on Page 94, that Image (d) is actually an illusion.
A. I'd need to see that -- I'd need to see that specimen first-hand to be able to make that assessment.
Q. So you can't offer an opinion to a reasonable degree of scientific probability or certainty that the image on Page 94, (d), is caused by an artifact.
A. There's no question I can demonstrate that through simple geometry. You know, it's just an extension of what's on Figure 21.
I can show that you can get a multi-layer optical illusion, if you will, by having a bias-cut specimen. There's no doubt.
Q. Have you attempted to reproduce this artifact in any of your images?
MR. THOMAS: Object to form of the question.
A. Yes. So in the bovine serum specimens, we definitely have some micrographs that show when you have an overlap of a proteinaceous material on top of

Page 118

the outside perimeter of the fiber, that you can have the illusion of blue granules in some sort of protein crust.

Q. What image are you referring to in your report?

A. I'm trying to find it right now. I can rattle off the file name when you're ready.

Q. Ready.

A. Okay. 157183_serum_R -- as in Robert -- _63X_H&E_ANA --

(Discussion held off the record.)

A. -- _06-imageexport40. And then I'm not going to make you go through that whole thing again, but the next one is --

(Discussion held off the record.)

A. -- imageexport16.

Q. And that's not in your expert report. That's just a microphotograph?

MR. THOMAS: Object to the form of the question.

A. It would certainly be in the -- it is, actually. One of them is. So Figure 14 (b), as in boy, would be one of them. And, likewise, Figure 15 (a) and (b) show overlapping of the bovine serum -- the

Page 119

fixed bovine serum with the mesh specimen.

Q. Doctor, if you turn to -- let's look at your protocol for the chemical oxidizing experiment that you did.

A. Okay. (Witness complies.)

Q. Okay. Do you have it in front of you?

A. I do. I just want to make sure we're working off the same document. So mine says "Guelcher Chemical Oxidation Protocol".

Q. Right. And, again, was it your -- the purpose of following Dr. Guelcher's protocol was to see if -- was, again, I guess, to use it as a control?

A. We were -- we wanted to actually include a chemical oxidation technique in addition to the QUV technique.

Q. Okay. And so you were attempting to see if you could produce the results of Dr. Guelcher.

MR. THOMAS: Object to form of the question.

A. No, not necessarily. We were using it as a method, an established method in the literature for oxidizing polypropylene-based materials. That's all. Chemically oxidizing polypropylene-based material.

Q. And you actually did find evidence in your FTIR analysis of the chemically oxidized samples of

Page 120

oxidation.

A. There was some oxidation species, correct.

Q. Okay. So you were actually able to begin the oxidation process using the chemicals in your protocol.

A. Yes. We found some evidence of oxidation.

Q. And were you trying to mimic the in vivo environment where these meshes are placed in a woman's body?

MR. THOMAS: Object to the form of the question.

A. No, not at all.

Q. Did any of your experiments mimic the in vivo environment of a woman's body?

A. No.

Q. If you look at your protocol, you actually added a step to -- to Dr. Guelcher's protocol, didn't you?

A. Can you just orient me so we can save time.

Q. Okay. Let's go ahead and mark as exhibit -- mark as an exhibit the Guelcher Chemical Oxidation Protocol.

(MacLean Deposition Exhibit 19 - Guelcher Chemical Oxidation Protocol - marked for identification.)

Page 121

MR. THOMAS: Do you have an extra one, Dan? What number did we mark that?

THE WITNESS: It was 19.

MR. THORNBURGH: 19.

Q. In your protocol, you used ultrasonic cleaning, right?

A. Can you just -- again, just for sake of time, just orient me to what number or what page you're on.

Q. Okay. So if we're on Exhibit 19, do you see the top, you talk about the equipment and supplies. Then you talk about the procedure.

A. Yes.

Q. At the bottom of Page 1.

A. (Witness nods head.)

Q. And then you talk about on Page 2 the chemical oxidation protocol.

A. Yes.

Q. And you go through the protocol, and you discuss on Section 6, sonicating, if necessary, to remove any cobalt chloride crystals.

A. Yes. Correct.

Q. Did you sonicate any of the chemical oxidation samples or the chemically treated samples?

A. I believe so. We did. We tried to remove

Page 122

some of the cobalt crystals that were adhered to some of the fibers.
Q. Okay. And you did that in an ultrasonic bath or --
A. We did.
Q. Okay. And what type of cleaning solution did you use?
A. I believe it was just distilled water.
Q. So you put the samples into the ultrasonic bath with distilled water?
A. Correct.
Q. No other ultrasonic fluid was used?
A. No.
Q. You'd agree that that's a different protocol than was used by Dr. Guelcher?
A. I don't recall. I don't have them side by side. But it would -- it doesn't affect the results. You're just trying to remove these crystals that are now sitting on the surface. There's no interaction between them.
Q. Well, why did you add this step if it wasn't part of Dr. Dunn and Guelcher's protocol?
A. Because we wanted to isolate the fibers, and we had so many of the cobalt crystal -- crystals --

Page 123

excuse me -- cobalt chloride crystals that were adhering to the surface that we wanted to remove them. That's all.
Q. Did you use ultrasonic cleaning in any of the UV-treated samples?
A. We did not.
Q. Okay. And have you read any publications that discuss how using -- or how the abrasive steps are taken in cleaning explanted samples can actually remove the degraded surface layer?
MR. THOMAS: Object to form of the question.
A. I know that when some people have cleaned explanted specimens, that there is a removal of this crust, if that's what you're asking me.
Q. Did you, in any of your experiments that you conducted -- were you ever asked to see whether or not the cleaning steps that are used by, for example, Dr. Timms (phonetic) can actually remove the oxidized degraded surface layer?
A. That's a question for Dr. Timms. I didn't do that work.
Q. You weren't asked to do that work?
A. I was not.
Q. Turn to Table 1 of your expert report in Wave

Page 124

1.
A. And what page is that on?
Q. It's actually your supplemental report, Page 11.
A. (Witness complies.) Okay.
Q. This Table 1 discusses the PROLENE samples that were processed --
A. Correct.
Q. -- in your experiment.
A. Correct.
Q. And you expose -- we talked about all the samples that were exposed to QUV resin. But if you look at Column -- let's see here. Actually, strike that.
Let's just turn real quick to Page 176 of your supplemental report.
A. (Witness complies.) 176.
Q. Is this where your FTIR analysis begins on -- in the experiments that you conducted?
A. Correct.
Q. Okay. And on Page 176, you have a number of controls?
A. I do.
Q. And then on Page 177, you have additional

Page 125

controls. And then you get, finally, to Page 180, it looks like; the FTIR related to the QUV experiment.
A. Yes.
Q. And these are samples that are actually treated with QUV, right?
A. Correct.
MR. THOMAS: It's 11:45.
(Discussion held off the record.)
Q. If you look at the images on Page 180, the FTIR, you have identified some carbonyls that are consistent with degradation, right?
MR. THOMAS: Object to form.
Q. And oxidation.
MR. THOMAS: Object to form of the question.
A. I will say that there are carbonyls where I would expect them to be between 16- and 1800.
Q. Where you would expect them to be in a oxidized material, polypropylene material, right?
A. Correct. That would be one -- that would be one indication or that would be one reason why carbonyls would form in that area.
Q. Okay. And it's a broad band -- I think you said a broad band, between 1600 -- 1650 and 1800?
A. Yeah. More or less.

Q. Okay. And that would be -- it's your opinion, as a polymer scientist, that a carbonyl within that location would be consistent with oxidized polypropylene.

MR. THOMAS: Object to the form of the question.

A. Let's be clear about this. It's because I know the environment that those specimens were put into. So I can't just look at this spectrum in isolation and say I achieved oxidation.

It's because I know it went under QUV, I know it started in the pristine state. And once I have those additional factors known to me, and there's no other variables, then, yes, I can ascribe that to oxidation.

Q. On your chemical-treated samples --

A. Um-hum.

Q. -- where is the FTIR in your report?

A. I don't see it, so it's probably on the thumb drive.

Q. Why didn't you include the FTIR in your report from the chemically treated samples?

A. No reason. Could have just been an oversight. It's definitely in our produced data set.

Q. Was the FTIR findings of the chemical -- chemically treated samples consistent with the FTIR band seen in the QUV-treated samples?

A. I wouldn't --

MR. THOMAS: Object to the form of the question.

A. I wouldn't use the word "consistent" or "inconsistent". There were, I would say, different oxidation species that developed under chemical oxidation.

Q. Okay. Which oxidation species developed under chemical oxidation?

A. We saw hydroxyl formation in the 32- to 3500 range, and we saw C single bond O in some -- I think in most, if not all, of the specimens at 1050 and 1150.

MR. THOMAS: I have to stop you, Dan, because I have to ask a few questions, and I have to go. You've been three hours.

(Discussion held off the record.)

BY MR. THORNBURGH:

Q. Where were the carbonyl peaks in the chemically treated samples? Where were they located on the spectrum?

A. Well, carbonyl peaks would show up like we

talked about; anywhere from, say, 1650 to 1800.

Q. Okay. And how is it different, the QUV-treated, how is that different than the chemical-treated?

MR. THOMAS: Object to form of the question.

A. One is oxidized through chemicals, one is oxidized through UV radiation.

Q. So the mechanism of action is different?

A. I would say the energy imparted to induce oxidation is different. The energy method.

Q. And I think you said this earlier, but the QUV-treated samples that you -- experiment that you performed, that doesn't happen in the human body.

A. Well, with the exception of the eye, if we're just talking about pelvic meshes, you're correct.

Q. So the experiments that you conducted in this case -- I think you testified to this -- did not mimic the environment of the human body.

A. Correct. And we didn't attempt to do that.

MR. THORNBURGH: Okay.

MR. THOMAS: Finished?

MR. THORNBURGH: Yes.

(Discussion held off the record.)

EXAMINATION

BY MR. THOMAS:

Q. Doctor, I just have a couple questions for you.

If you turn to Exhibit No. 14, which is your Wave 1 report, on Pages 36 and 37 there is discussion of papers by Bracco and Imel.

A. Correct.

Q. Is that correct?

A. That is correct.

Q. Are those additions to this report?

A. They are. I missed those in my first pass-through. I missed Bracco and Imel; would be additions.

Q. Those are the only additions beyond what you described to Mr. Thornburgh before?

A. That is correct.

(MacLean Deposition Exhibit 20 - Publication by Benight, MacLean, Garcia, and Moll - marked for identification.)

Q. I want to hand you now what I've marked as MacLean Exhibit No. 20, a document that's contained in what we've produced to Plaintiffs on the thumb drive.

Page 130

What is Exhibit No. 20?
A. It is a pending publication regarding the work that we did last fall.
Q. And when you say the "work that you did last fall", is that the work that you did in the Mullins case?
A. It is.
Q. And what was your intent when you submitted Exhibit No. 20?
A. To get published in a peer-reviewed conference proceeding.
Q. Did you change any of the procedures, the data, the findings in Exhibit No. 20, as reported in your report from the Mullins case, before submitting it for publication?
MR. THORNBURGH: Objection.
A. I did not.
Q. Okay. And to what journal was it submitted?
A. This is -- this was submitted to the medical division, medical device division of the Society of Plastics Engineers.
Q. And has it been accepted for publication?
A. It has.
Q. Was it accepted without change?

Page 131

A. Without change.
Q. And when will it be published?
A. It will be published at the end of May.
Q. And will it be presented?
A. It will be -- also be presented at the end of May.
Q. And where will it be presented?
A. In Indianapolis.
Q. At what proceeding?
A. At the an.tech. conference. It's the annual technical conference for the Society of Plastics Engineers.
Q. And what is an.tech. conference to plastics engineers?
A. It's where industrial polymer scientists and researchers come together for three or four days to author publications and have seminars and technical symposium, things like that.
Q. And who will present that paper?
A. It hasn't been decided, but it will be either Dr. Benight or myself.
MR. THOMAS: That's all the questions I have. Thank you.
MR. THORNBURGH: Can I ask two questions about this?
MR. THOMAS: Yes.

Page 132

EXAMINATION
BY MR. THORNBURGH:

Q. Doctor, regarding the publication, you said it was accepted by the medical device division of the --
A. Society of Plastics Engineers. SPE, it's informally known as.
Q. Are they peer-reviewed?
A. They are.
Q. Okay. And did you attempt to submit this publication to any other journal?
A. Not at this time.
Q. And on the last page of this abstract, you note the conflict of interest.
A. On the last page of the publication, yes, I note a conflict of interest disclosure.
Q. And did you disclose that you were being paid as an expert to defend Ethicon in claims that its mesh material oxidized and degraded, causing injury to patients?

Page 133

MR. THOMAS: Object to the form of the question.
A. I disclosed what's written here in those two or three sentences under the disclosure.
MR. THOMAS: Okay. That's all. I've got to go.

(Deposition concluded at 11:54 p.m.)

* * * * *

STATE OF NEW YORK)
) SUPREME COURT
COUNTY OF NEW YORK)

I, Janis L. Ferguson, RPR, CRR, a Notary Public in and for the State of New York, do hereby certify:

That the witness whose testimony appears herein before was, before the commencement of his/her testimony, duly sworn to testify the truth, the whole truth, and nothing but the truth; that the testimony was taken pursuant to notice at the time and place herein set forth; that said testimony was taken down in shorthand by me and after, under my supervision, transcribed into the English language, and I hereby certify the foregoing testimony is a full, true, and correct transcription of the shorthand notes so taken.

I further certify that I am neither counsel for, nor related to any parties to said action, nor in any way interested in the outcome thereof.

IN WITNESS WHEREOF, I have hereunto subscribed my name this 20th day of April, 2016.

Janis L. Ferguson, RPR, CRR
Notary Public in and for the State of New York

My Commission expires: 5/28/2017
Registration No. 01FE6282686